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# **Government Policy Relating to Hepatitis B in New Zealand 1970–2005**

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## ABSTRACT

Hepatitis B emerged as a significant public health problem in New Zealand in the early 1980s. Initially seen as an infectious threat to transfusion recipients and an occupational hazard for health care workers, epidemiological studies revealed the unexpectedly high prevalence of the disease, particularly among Maori children, who were found to be at higher risk of developing chronic hepatitis B and its longterm complications. Despite these findings, however, factors other than scientific research influenced policy makers. The Health Department was reluctant to acknowledge that New Zealand, unlike other Western countries, had a high prevalence of a ‘third world’ disease. An effective vaccine was available from late 1982, but in an era of increasing fiscal constraints, the Health Department cited its high cost as a barrier to state-funded immunisation.

From the mid-1980s community-based health activists and prominent Maori, rather than public health officials, drove the hepatitis B policy agenda. Individual policy players proved more influential than central policy advisors; nevertheless, in the absence of a comprehensive control strategy, attempts at hepatitis B prevention faltered. Despite the introduction of universal childhood hepatitis B immunisation in 1990, vaccine uptake was persistently poor, particularly among ‘high risk’ children. Equally, a three-year screening programme to identify and follow up hepatitis B carriers, introduced in 1999 in spite of strong opposition from official advisors, reached less than half of its targeted population.

Adopting a chronological approach and drawing on archival sources and oral history interviews, this thesis examines the factors that shaped the formation of hepatitis B policy in New Zealand from 1970, when the first test for hepatitis B provided the means of protecting the blood supply, to 2005 when policy makers finally took a firm stand on the management of hepatitis B infected health care workers. It considers the debates around the introduction of hepatitis B immunisation and screening policies and locates the individuals and issues that influenced those debates within an international context.

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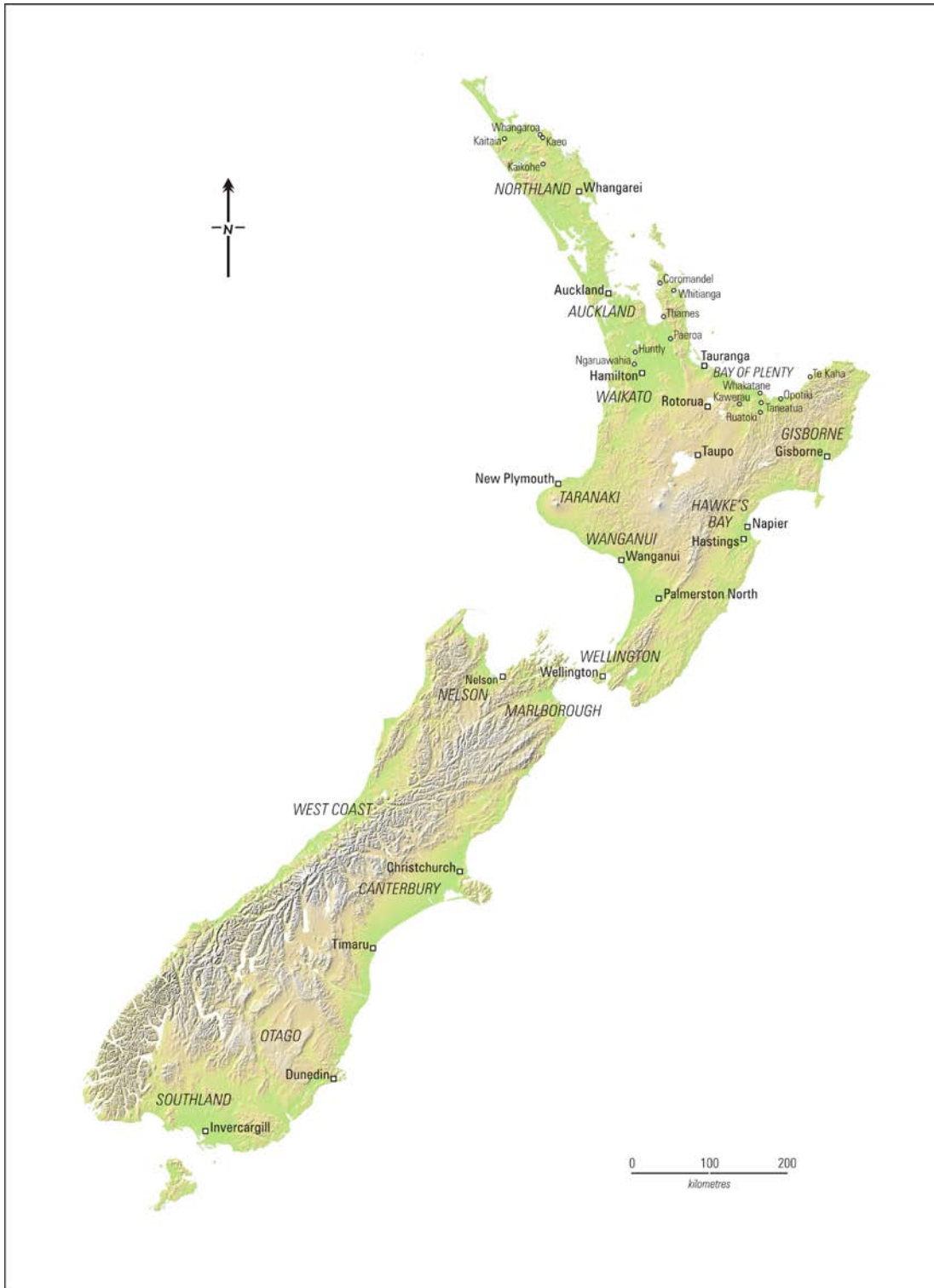
## LIST OF ABBREVIATIONS

ACC	Accident Compensation Commission
ACIP	Advisory Committee on Immunization Practices (US)
AGH	Advisory Group on Hepatitis (UK)
AHB	Area Health Board
AIDS	Acquired Immune Deficiency Syndrome
AJHR	<i>Appendices to the Journals of the House of Representatives</i>
ANZA	Archives New Zealand, Auckland
ANZW	Archives New Zealand, Wellington
ATL	Alexander Turnbull Library
CDC	Centers for Disease Control
CDCAC	Communicable Disease Control Advisory Committee
CDNZ	<i>Communicable Disease New Zealand</i>
CDR	<i>Communicable Disease Report (UK)</i>
CSL	Commonwealth Serum Laboratories
DGH	Director-General of Health
DHSS	Department of Health and Social Services (UK)
EAGA	Expert Advisory Group on AIDS (UK)
EAC	Epidemiology Advisory Committee
EP	<i>Evening Post</i>
HIV	Human Immunodeficiency Virus
HBCP	Hepatitis B Control Programme
HBCT	Hepatitis B Control Team
HRANZ	Health Regulatory Authorities of New Zealand
HRU	Hepatitis Research Unit, Whakatane
JAMA	<i>Journal of the American Medical Association</i>
MMWR	<i>Morbidity and Mortality Weekly Report</i>
MWWL	Maori Women's Welfare League
MRC	Medical Research Council
NEJM	<i>New England Journal of Medicine</i>
NHI	National Health Institute
NZCDC	New Zealand Communicable Disease Centre
NZH	<i>New Zealand Herald</i>
NZMJ	<i>New Zealand Medical Journal</i>
NZPD	<i>New Zealand Parliamentary Debates</i>
PHC	Public Health Commission
MSD	Merck Sharpe and Dohme Limited
SKF	Smith Kline and French Limited
TAC	Transfusion Advisory Committee
TVNZ	Television New Zealand
UKAP	UK Advisory Panel for healthcare workers infected with bloodborne viruses
WDFP	Women's Division of Federated Farmers
WHO	World Health Organization

## GLOSSARY

Antibody	A protein made by the body's immune defence system to fight off infection. Antibodies are made after the body reacts to infection with the hepatitis B virus.
Antigen	The protein part of an infecting organism that acts as a signal for the body to start producing antibodies. The hepatitis B antigen is present in the bloodstream of people with hepatitis B virus infection.
Carrier	Person who harbours an infection long term.
Chronic hepatitis B	Infection with hepatitis B for more than six months.
Cirrhosis	Serious liver condition characterised by scarring of the liver, which can lead to liver failure and death.
Fulminant hepatitis	Acute liver failure which is frequently fatal.
Hepatitis B immunoglobulin	Antibodies derived from the blood of hepatitis B carriers that provide passive protection against hepatitis B.
Hepatocellular carcinoma	A cancer of the liver ('primary liver cancer') that is invariably fatal unless detected early.
Hui	Gathering or meeting.
Iwi	Tribe.
Jaundice	Yellowish discolouration of the body, including the whites of the eyes and the skin.
Marae	Meeting place; the courtyard in front of the meeting house or wharenuī.
Pakeha	Non-Maori; European New Zealander.
Prevalence	Proportion of a population that have a disease or condition at a given moment in time.
Whanau	Extended family; family members sharing blood links through a common ancestor.

# MAP OF NEW ZEALAND



Source: Igor Drecki, School of Environment, University of Auckland, 2009.

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## CHAPTER ONE

### INTRODUCTION

Progressive studies over the last few years on the prevalence of this disease have surprised and dismayed us all, showing as they do how New Zealand has the highest rate of hepatitis B of any Westernised country ...<sup>1</sup>

On 9 December 1986, Health Minister Michael Bassett announced the first major expansion of New Zealand's hepatitis B immunisation programme. Bassett's frank admission of New Zealand's unique status as a developed nation with a high prevalence of a 'third world' disease revealed little of the public controversy that had preceded his decision to expand the hepatitis B immunisation policy. Nor did his brief reference to the collective 'surprise and dismay' over the unexpectedly high rates of hepatitis B virus infection reflect the degree of resistance to the notion that New Zealand had a serious public health problem.<sup>2</sup> The Health Department did not advocate universal childhood hepatitis B immunisation, despite studies that revealed that the disease was endemic among Maori children in many North Island communities, and that the Eastern Bay of Plenty had the highest rate of infected European children recorded worldwide.<sup>3</sup> These findings challenged departmental perceptions of New Zealand as a 'first world' nation, and tested its ability to respond to a public health problem which impacted on the Maori population in particular.

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<sup>1</sup> Minister of Health, 'Notes for speech in opening the workshop for Expanded Immunisation Programme for Hepatitis B', 9 December 1986, ABQU 632 W4452/701 131/171/4 62751, Archives New Zealand, Wellington (ANZW).

<sup>2</sup> *ibid.*

<sup>3</sup> A. Milne, 'Viral hepatitis in the eastern Bay of Plenty', *New Zealand Medical Journal* (NZMJ), 92, 13 August 1980, pp.87-91; A. Milne, C. D. Moyes, 'Hepatitis B carriage in children', NZMJ, 96, 13 April 1983, pp.238-41; Y. E. Hermon, I. K. Mushawar, M. I. Tobias, 'Hepatitis B infection in New Zealand children', NZMJ, 97, 26 December 1984, pp.887-9; A. Milne, G. K. Allwood, C. D. Moyes, N. E. Pearce, C. R. Lucas, 'Prevalence of hepatitis B infections in a multiracial New Zealand community', NZMJ, 98, 10 July 1985, pp.529-32.

The reluctance of health officials to act on hepatitis B forms a major recurring theme in this thesis, which examines hepatitis B policy in New Zealand from 1970 to 2005, and which provides an account of how policy was made and the issues that influenced the directions that it took. As background to policy making in New Zealand, it considers the development of hepatitis B policy in other countries, particularly the United Kingdom (UK) and the United States (US), and examines the ways in which international guidelines and recommendations influenced local policy makers. Factors that have shaped policy are explored: evidence-based research, widely regarded as the basis of rational health policy making, is shown to have had little direct impact on the formulation of hepatitis B policy. In this respect, the development of hepatitis B policy in New Zealand appeared to mirror the policy making process in the UK. In her 1995 PhD thesis on the relationship between medical research and hepatitis B policy in the UK from the 1940s, Jennifer Stanton concluded that ‘medical research rarely played a direct role in shaping policy’.<sup>4</sup>

In New Zealand, political and economic factors had a key influence on the development of hepatitis B policy. In the 1980s, a decade of budget blow outs and cuts in public health funding, the high cost of the hepatitis B vaccine acted as a strong deterrent to the introduction of a nationwide childhood immunisation programme. Furthermore, by the mid-1980s, fears of another blood borne epidemic had taken hold among health officials. Acquired Immune Deficiency Syndrome (AIDS), described by Bassett in late 1986 as a ‘deadly threat to our very future as a nation’, took precedence for government funding while hepatitis B was regarded as a relatively low public health priority.<sup>5</sup>

Broader societal changes influenced policy too. The Maori ‘renaissance’ of the 1970s and the increasing participation of Maori in the delivery of health services in the 1980s and 1990s saw Maori take a more critical stance on the planning and delivery of hepatitis B immunisation and screening programmes. Moreover, as Alison Day observed in her 2008

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<sup>4</sup> J. M. Stanton, ‘Health Policy and Medical Research: Hepatitis B in the UK since the 1940s’, PhD thesis, London School of Hygiene and Tropical Medicine, 1995, p.287.

<sup>5</sup> Minister of Health, News Release, ‘Reflections on the Health Portfolio – 1986’, 26 December 1986, Bassett papers, 88-289-61, Alexander Turnbull Library (ATL), Wellington.

PhD thesis on child immunisation policy in New Zealand, with the rise of the consumer movement in health during the 1970s and 1980s, parents throughout the country began to ‘ask for and expect more detailed information on vaccine effects and risks’.<sup>6</sup>

Changing political philosophies also contributed to the shape and delivery of hepatitis B policy. From the mid-1980s and throughout the 1990s, policy making occurred against a background of major organisational change within the New Zealand health system as it was restructured by the Fourth Labour Government (1984–1990), then radically reformed by the subsequent National Government in the 1990s.<sup>7</sup> Universal access to public health services, a cornerstone of the New Zealand welfare state since its inception in 1938, came under threat as firstly the Labour Government, and then the National Government, introduced neo-liberal economic reforms, including ‘user pays’ services, to the health system. In a political climate that endorsed greater self-reliance and less state intervention, the Health Department agreed to a private company providing user-pays hepatitis B immunisation for school children, despite the obvious drawbacks for children from poorer homes, many of whom were Maori.<sup>8</sup>

Finally, it will be argued that key policy players were of crucial importance in the policy making process. Successive ministers of health, senior health officials, ministerial advisory committees, Maori politicians and health professionals, and community-based health activists, will be seen to play a decisive role in setting policy agendas and determining public health priorities. From this perspective, Betsy Thom’s succinct observation on the ‘dynamics of interaction’ between policy players in the alcohol field in

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<sup>6</sup> A. S. Day, ‘Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920–1990’, PhD thesis, University of Auckland, 2008, p.295.

<sup>7</sup> R. Gauld, *Revolving Doors: New Zealand’s Health Reforms – the Continuing Saga*, 2<sup>nd</sup> edn, Wellington, 2009, p.37.

<sup>8</sup> See Chapter Six for further discussion of user pays immunisation schemes and their impact on hepatitis B policy. Statistics compiled by health researchers in the 1970s and 1980s confirmed that two-thirds of Maori were in the lowest socio-economic brackets. See for example, E. W. Pomare and G. M. de Boer, *Hauora: Maori Standards of Health: A Study of the Years 1970–1984, Special Report Series No 78*, Wellington, 1988, pp.39-49.

the UK from 1950 to 2005 applies just as well to the development of hepatitis B policy in New Zealand: 'Policy is made by people, not by science.'<sup>9</sup>

## **Hepatitis B**

Hepatitis B is a potentially fatal liver disease caused by the hepatitis B virus. The virus, which is highly infectious, is found in blood and other body fluids. It can be transmitted in a variety of ways: from mother to baby at birth, during the rough and tumble of childhood play, during sexual intercourse and close physical contact, through blood transfusion and organ donation, and through contaminated needles and syringes. Because the hepatitis B virus can survive for long periods outside the human body, infection from common household items such as toothbrushes and razors can also occur.<sup>10</sup> Yet despite its high infectivity and multiple modes of transmission, hepatitis B was not recognised as a separate disease until the mid-twentieth century.

Initially, hepatitis B, or 'serum' hepatitis, was seen as a variant of 'common infectious hepatitis', which occurred regularly in Western countries, often in epidemic form.<sup>11</sup> The earliest report proposing a separate type of hepatitis spread by human serum was published in Germany in the late nineteenth century.<sup>12</sup> Subsequently, in the early twentieth century, sporadic outbreaks of serum hepatitis were noted among patients receiving injection therapy for syphilis and diabetes, and again, in the 1930s, hepatitis cases were reported after the use of serum-based vaccines against measles and yellow fever.<sup>13</sup> It was not until 1942, however, when more than 50,000 US servicemen were

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<sup>9</sup> B. Thom, 'Who Makes Alcohol Policy? Science and Policy Networks 1950-2000', in V. Berridge, ed., *Making Health Policy: Networks in Research and Policy after 1945*, Amsterdam, 2005, p.75.

<sup>10</sup> G. L Mandell, J. E. Bennett and R. Dolin, eds, *Principles and Practice of Infectious Diseases*, 6<sup>th</sup> edn, Philadelphia, 2005, p.1428.

<sup>11</sup> Infectious hepatitis, later renamed hepatitis A, is caused by the hepatitis A virus which is spread in contaminated food and water supplies.

<sup>12</sup> A. Lurman, 'Eine ikterus epidemie', *Berliner klinische Wochenschrift*, 12 January 1885, pp.20-3.

<sup>13</sup> See for example, J. H. Stokes, R. Ruedemann, W. S. Lemon, 'Epidemic infectious jaundice and its relation to the therapy of syphilis', *Archives of Internal Medicine*, 26, 1920, pp.521-43; A. Flaum, H. Malmros, E. Persson, 'Eine nosocomiale Ikterus-epidemie', Supplement 16, 1926, pp.544-53. For 'inoculation' hepatitis, see G. M. Findlay, F. O. MacCallum, 'Notes on acute hepatitis and yellow fever immunization', *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 3, 3 November 1937, pp.297-308; G. M. Findlay, F. O. MacCallum, 'Hepatitis and jaundice associated with immunization against certain virus diseases', *Proceedings of the Royal Society of Medicine*, 31, 1938, pp.799-805.

hospitalised for serum hepatitis following mass immunisation against yellow fever, that intensive research was undertaken in the US and the UK to determine the exact nature and cause of the disease.<sup>14</sup>

Wartime research gained greater urgency after the discovery that blood and plasma transfusions, crucial in the treatment of military and civilian casualties, could also transmit serum hepatitis.<sup>15</sup> Nonetheless, for another two decades, the virus responsible for hepatitis B (the name adopted for the disease after World War Two) proved impossible to isolate.<sup>16</sup> The elusive nature of the virus hindered scientific and epidemiological investigations into hepatitis B, which was primarily seen as an iatrogenic disease transmitted by blood transfusion and serum-based vaccines.<sup>17</sup>

While the lack of a laboratory test to detect hepatitis B clearly prevented confident diagnosis of the illness, it did not in itself explain the limited medical understanding of the disease. Given its high infectivity, it seems reasonable to ask how doctors overlooked cases of hepatitis B that occurred in people who had no contact with the health care settings which were regarded as the primary source of infection. Even in countries later found to have a low prevalence of hepatitis B, such as the UK, the US, and Northern Europe, there were pockets of high prevalence among certain social and ethnic groups.<sup>18</sup> Yet this was not simply a case of medical myopia or the uncritical acceptance of scientific ‘facts’. The peculiarities of hepatitis B meant that the majority of community-

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<sup>14</sup> At least 100 servicemen died during the 1942 epidemic which was extremely widespread; once troops had been vaccinated, they were deployed to the Pacific, the UK and South-East Asia. ‘Editorial: Jaundice following yellow fever vaccination’, *Journal of the American Medical Association (JAMA)*, 119, 14, 1 August 1942, p.1110; L. Seeff, W. Beebe, J. H. Hoofnagle, J. E. Norman, Z. Buskell-Bales, J. G. Waggoner, N. Kaplowitz, R. S. Koff, J. L. Petrini, E. R. Schiff, J. Shorey, M. M. Stanley, ‘A serologic follow-up of the 1942 epidemic of post-vaccination hepatitis in the United States Army’, *New England Journal of Medicine (NEJM)*, 316, 16, 16 April 1987, pp.965-70.

<sup>15</sup> P. B. Beeson, ‘Jaundice occurring one to four months after transfusion of blood or plasma’, *JAMA*, 24 April 1943, pp.1332-4.

<sup>16</sup> F. O. MacCallum, ‘In Scientific Discussions: Infective hepatitis’, *Lancet*, 20 September 1947, pp.435-6.

<sup>17</sup> See, for example, R. H. Moser, ‘Diseases of medical progress’, *NEJM*, 255, 13, 27 September 1956, p.606. Moser included serum hepatitis among the ‘disease[s] of medical progress’ that accompanied the ‘potent new therapeutic agents [and] improved surgical procedures’ that characterised modern medicine.

<sup>18</sup> These included groups as varied as drug users, homosexual men, and immigrants from high prevalence countries in Sub-Saharan Africa, China and South-East Asia.

acquired infection was asymptomatic and therefore not apparent either to doctors or to those infected by the virus.

The apparent absence of hepatitis B, even in countries later found to have a high prevalence of the disease, can be attributed to a number of factors. Firstly, it is difficult to distinguish between different types of acute viral hepatitis infection. Without the use of laboratory tests, cases of serum hepatitis can easily be mistaken for infectious hepatitis (or hepatitis A) as both diseases have similar clinical features: malaise, joint pain, lack of appetite, nausea and vomiting, abdominal discomfort and jaundice, or yellowing of the skin and the whites of the eyes. Secondly, the majority of recently acquired infections are so mild that they go unnoticed. Signs of recently acquired infection are rare in babies and uncommon in children. Even among adults, only 30 to 40 per cent of those infected show overt signs or symptoms of the disease, and while hepatitis B virus infection can be life-threatening, most adults recover completely.<sup>19</sup> Thirdly, adults who have developed chronic hepatitis B virus infection (chronic carriage) as babies or preschool children are at high risk of lifelong infection with a significant risk of developing cirrhosis and liver cancer. However, many decades may pass between the original infection and its longterm consequences. Lastly, chronic carriers of the virus, who form the main reservoir of infection, are almost always asymptomatic, giving no indication that they have been infected.<sup>20</sup>

Once the hepatitis B test became widely available in the early 1970s, prevalence studies showed that hepatitis B was not only a global health problem, but that it had a markedly unequal geographic distribution.<sup>21</sup> Western countries had the lowest prevalence of hepatitis B carriers, while developing countries in Sub-Saharan Africa, South-East Asia and the Pacific carried the major burden of disease.<sup>22</sup> In the mid-1970s, New Zealand was

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<sup>19</sup> G. L. Mandell, J. E. Bennett and R. Dolin, eds, *Principles and Practice of Infectious Diseases*, p.1428.

<sup>20</sup> Ministry of Health, *Immunisation Handbook 2006*, Wellington, 2006, pp.127-8.

<sup>21</sup> By the mid-1970s it was estimated that at least 120 million people worldwide were chronic carriers of hepatitis B. W. Szmunes, 'Recent advances in the study of the epidemiology of hepatitis B', *American Journal of Pathology*, 81, 3, December 1975, pp.629-49.

<sup>22</sup> In the mid-1970s, the prevalence of hepatitis B carriage in the US, the UK and Australia, all 'population[s] of British origin', was estimated to be less than 1 per cent, while prevalence rates ranged

predominantly populated by people of European descent; however, indigenous Maori comprised over ten per cent of the population, and there were more than 60,000 Pacific residents in the total population of 3.13 million.<sup>23</sup> Nevertheless, health officials, who were accustomed to considering New Zealand's first world status rather than its geographical locus or changing demographics, assumed that local hepatitis B prevalence rates would be in line with other developed countries.<sup>24</sup>

From a policy perspective, beliefs relating to the disease that took root in New Zealand's Health Department in the 1970s proved hard to shift. Coupled with the 'undercover' qualities of hepatitis B, they shaped official perceptions of the extent of the problem in New Zealand, and structured policy responses.<sup>25</sup> In the 1980s, community health activists challenged the supposedly firm epidemiological facts of hepatitis B, raising questions about the nature of the evidence on which policy was based, and the appropriate place of a disease that primarily affected Maori on a crowded policy agenda. These questions, which formed the backdrop to policy decisions over the next two decades, will be explored in this study.

### **Historical studies of hepatitis B**

Before the late 1980s, hepatitis B received no attention from historians, despite its global importance as an infectious disease. In contrast, every aspect of AIDS, which has striking similarities to hepatitis B, has been scrutinised since it first appeared in the US in the

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from two to fifteen per cent in Eastern Europe, the USSR, Asia, Africa, and the Pacific. O. Sobeslavsky, 'HBV as a Global Problem', in G. N. Vyas, S. N. Cohen, and R. Schmid, eds, *Viral Hepatitis: A Contemporary Assessment of Etiology, Epidemiology, Pathogenesis and Prevention*, Philadelphia, 1978, p.348.

<sup>23</sup> In the 1976 census, 356,000 people identified themselves as Maori. Statistics New Zealand, 'Historical Population Estimates', online, nd, available at:

[http://www.stats.govt.nz/methods\\_and\\_services/access-data/tables/historical-population.aspx](http://www.stats.govt.nz/methods_and_services/access-data/tables/historical-population.aspx) (29 January 2010); J. Belich, *Paradise Reforged: A History of the New Zealanders*, Auckland, 2001, p.533.

<sup>24</sup> See for example, Derek Dow's history of the Health Department, in which he explained that New Zealand saw itself as a 'world leader' in public health, with a 'proud record in the WHO'. D. A. Dow, *Safeguarding the Public Health: A History of the New Zealand Department of Health*, Wellington, 1995, p.239.

<sup>25</sup> In 1985, the *NZ Listener* published an article on hepatitis B with the evocative title 'The undercover epidemic'. L. Guerin, 'The undercover epidemic', *NZ Listener*, 24 August 1985, pp.16-8.

early 1980s.<sup>26</sup> Lacking appeal as a subject in its own right, hepatitis B initially assumed historical relevance as a comparative case study with AIDS.

‘AIDS’, Virginia Berridge observed in 1996, ‘even in its early stages, brought history in its train’.<sup>27</sup> Indeed, within a decade of its discovery, HIV/AIDS had been the stimulus for a large body of historical work.<sup>28</sup> To begin with, historical analysis sought to link the development of AIDS policy with its historical antecedents. In 1988, for example, Roy and Dorothy Porter explored older conflicts between the state and the individual to highlight the historical debate over ‘public power and private liberty’ that preceded the apparently new policy dilemmas raised by AIDS.<sup>29</sup> Similarly, in 1989 Charles Rosenberg re-visited the experience of past epidemics to illustrate the range of policy responses possible during a new type of epidemic.<sup>30</sup> In reprising this phase of the history of AIDS, Berridge concluded that ‘the “lesson of history” was to the fore’.<sup>31</sup>

American historian William Muraskin, the major contributor to the historiography of hepatitis B, published his first paper on the disease in 1988, at the height of this self-reflective period of AIDS history.<sup>32</sup> While he described hepatitis B as ‘a major disease in

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<sup>26</sup> Human immunodeficiency virus (HIV) and hepatitis B are distinct viruses, but they are both transmitted through sexual contact, blood-to-blood contact and mother-to-child transmission. Both viruses lead to chronic infection, although a minority of people infected with hepatitis B will become chronic carriers of the virus, whereas most people infected with HIV go on to develop severe immune deficiency (AIDS) within ten years. Australasian Society for HIV Medicine, *HIV/Viral Hepatitis: A Guide for Primary Care*, Sydney, 2001, p.9.

<sup>27</sup> V. Berridge, ‘Introduction: AIDS and Contemporary History’, in V. Berridge and P. Strong, eds, *AIDS and Contemporary History*, Cambridge, 1993, p.1.

<sup>28</sup> See, for example, R. Porter, ‘History says no to the policeman’s response to AIDS’, *British Medical Journal*, 293, 6562, December 1986, pp.1589-90; E. Fee and D. M. Fox, eds, *AIDS: The Burdens of History*, Berkeley, 1988; A. M. Brandt, ‘AIDS and metaphor: Towards the social meaning of epidemic disease’, *Social Research*, 55, 3, Autumn 1988, pp.413-32. A selection of books and essays published on the historical and social aspects of AIDS in the late 1980s is reviewed in V. Berridge, P. Strong, ‘AIDS and the relevance of history’, *Social History of Medicine*, 4, 1, 1991, pp.129-38. See, also, E. Fee and D. M. Fox, eds, *AIDS: The Making of a Chronic Disease*, Berkeley, 1992; C. Rosenberg, *Explaining Epidemics and Other Studies in the History of Medicine*, Cambridge, 1992.

<sup>29</sup> D. Porter and R. Porter, ‘The Enforcement of Health: The British Debate’, in Fee and Fox, *AIDS: The Burdens of History*, pp.97-120.

<sup>30</sup> C. E. Rosenberg, ‘What is an epidemic? AIDS in historical perspective’, *Daedalus*, 118, 2, Spring 1989, p.9.

<sup>31</sup> V. Berridge, ‘Introduction: AIDS and Contemporary History’, p.2.

<sup>32</sup> W. Muraskin, ‘The silent epidemic: The social, ethical and medical problems surrounding the fight against hepatitis B’, *Journal of Social History*, 22, 277, 1988, p.277-98.



its own right', Muraskin argued that it had gained significance as a result of 'its relationship to the AIDS crisis of the 1980s'.<sup>33</sup> In keeping with the broader impetus to uncover the 'lessons' offered by earlier epidemics, he explained that 'the fight against hepatitis B was a dress rehearsal for the problems raised by AIDS', and that 'the hepatitis B crisis helped set a precedent for how AIDS would be treated a few years later'.<sup>34</sup>

Muraskin made a contrast between the subdued reaction to hepatitis B in the US in the 1970s and the 'massive' public interest shown in AIDS in the 1980s.<sup>35</sup> Rather than use the wide disparity in fatality rates or the social and cultural context in which AIDS first emerged to account for the differing responses to the two diseases, he concluded that the US medical profession downplayed hepatitis B as a public health problem to avoid public debate on the problems posed by hepatitis B carriers, many of whom were health care workers.<sup>36</sup> In New Zealand in the 1970s, deliberations over hepatitis B were similarly confined to medical circles. However, as will be discussed, this appeared to reflect the narrow focus on hepatitis B as an occupational hazard of health care settings, rather than a deliberate strategy to limit public awareness of the disease.

Despite clear social and cultural differences, Muraskin's discussion of the factors that shaped hepatitis B policy in the US proved useful in considering the New Zealand Health Department's approach to hepatitis B immunisation in the early 1980s. In his analysis, Western perceptions of hepatitis B as a health problem primarily affecting high-risk adults, combined with the exorbitant cost of the vaccine (approximately 50 to 100 times more than other vaccines on the market) led international health authorities, including the World Health Organization (WHO) and the US Centers for Disease Control (CDC) to recommend selective immunisation policies for high risk groups.<sup>37</sup> The New Zealand

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<sup>33</sup> *ibid.*, p.277.

<sup>34</sup> *ibid.*, p.277; p.291. Over the following five years, Muraskin continued to develop this theme, most notably in his essay 'Hepatitis B as a model (and anti-model) for AIDS', in V. Berridge and P. Strong, *AIDS and Contemporary History*, pp.108-32.

<sup>35</sup> *ibid.*, p.277; p.280.

<sup>36</sup> *ibid.*, p.280.

<sup>37</sup> CDC, 'Recommendations of the Advisory Committee on Immunization Practices: Inactivated hepatitis B vaccine', *MMWR*, 31, 25 June 1982, pp.317-28; WHO, *Prevention of Liver Cancer: Technical Report Series No. 691*, Geneva, 1983.

Health Department, an active participant in the WHO, was influenced by these recommendations. In terms of controlling the spread of the disease, however, narrowly targeted immunisation policies had limited effect. Muraskin identified the ultimate futility of applying a high risk approach to hepatitis B immunisation, especially in communities and countries where the disease was endemic.<sup>38</sup>

Muraskin also emphasised the part played by individuals in shaping hepatitis B policy. His 1995 book on the activities of the International Hepatitis B Task Force, formed to promote hepatitis B immunisation in developing countries in 1986, drew attention to the contribution made by Dr James Maynard, a high-ranking CDC official.<sup>39</sup> Equally, Maynard was one of a number of medical experts to visit New Zealand in the mid-1980s, who had some influence on New Zealand hepatitis B policy.<sup>40</sup> Muraskin's 1995 article on Alexander Milne, a well-known New Zealand advocate of childhood hepatitis B immunisation, gave prominence to Milne's role in the introduction of the state-funded immunisation programme.<sup>41</sup> Despite his tendency to treat the main protagonists as 'heroes and villains' (he claimed that Milne had 'practically single-handedly force[d] a reluctant government to acknowledge the threat of hepatitis B and contain it'), Muraskin threw some light on the local narrative.<sup>42</sup> For example, he revealed the difficulties that Milne's strong views on hepatitis B control created, even for his close collaborators, an aspect of Milne's 'crusade' that was missing in the later accounts of New Zealand historians Alison Day and Vivien Edwards.<sup>43</sup>

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<sup>38</sup> W. Muraskin, 'The silent epidemic: The social, ethical and medical problems surrounding the fight against hepatitis B', pp.287-8. Muraskin developed this theme further in two later articles: 'Individual rights versus the public health: the controversy over the integration of retarded hepatitis B carriers into the New York public school system', *Journal of the History of Medicine*, 45, January 1990, pp.64-98; W. Muraskin, 'Individual rights vs the public health: the problem of the Asian hepatitis B carriers in America', *Social Science of Medicine*, 36, 3, 1993, pp.203-16.

<sup>39</sup> W. Muraskin, *The War Against Hepatitis B: A History of the International Task Force on Hepatitis B Immunization*, Philadelphia, 1995.

<sup>40</sup> See Chapter Six for a discussion of the influence of international experts on New Zealand's hepatitis B policy.

<sup>41</sup> W. Muraskin, 'Bucking the health establishment: Alexander Milne and the fight for a New Zealand hepatitis B immunization program', *Sociology, Science and Medicine*, 41, 2, 1995, pp.211-25.

<sup>42</sup> *ibid.*, p.211.

<sup>43</sup> A. S. Day, 'Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920-90', pp.218-29; V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, Wellington, 2007.

Jennifer Stanton's 1995 PhD thesis examined the relationship between hepatitis B policy and medical research in the UK from the 1940s.<sup>44</sup> Her own research had its origins in the changing historiographical approaches to AIDS in the early 1990s, which expanded to include an assessment of public health and social policy during the post-war period.<sup>45</sup> In both her thesis and a 1994 article that focused on the factors that shaped the UK's hepatitis B immunisation policy, Stanton explored issues central to this study: the rights of infected health care workers versus the protection of the public health and the tenuous links between research findings and health policy.<sup>46</sup>

Stanton explained that the UK response to the introduction of a costly hepatitis B vaccine in the early 1980s was to announce a restricted immunisation policy based on known risk groups. Policy decisions were not necessarily derived from technical advice; policy makers were influenced by the price of the vaccine, its limited availability, and the perception that the disease was a limited problem in the UK.<sup>47</sup> As she observed, 'when a 1983 cost-benefit analysis favoured wider use of the vaccine for gay men, policy did not change'. Yet in the early 1990s, moves were afoot to introduce universal childhood immunisation, despite low rates of infection in younger age groups. Stanton concluded that 'the apparently "pure" facts of epidemiology were constructed and reconstructed according to social relations, most immediately medical relations'.<sup>48</sup>

Stanton discussed how vaccine uptake in the UK in the 1980s, always expected to be low, was further reduced by resistance from health care workers, 'the chief targets of vaccine policy'.<sup>49</sup> As she explained, it could have been to health care workers' advantage to promote widespread immunisation once a vaccine became available. Yet, there was a determination to keep the rights of the individual to refuse pre-immunisation hepatitis B

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<sup>44</sup> J. M. Stanton, 'Health Policy and Medical Research: Hepatitis B in the UK since the 1940s'.

<sup>45</sup> *ibid.*, p.5. Stanton's research arose from a proposal put forward to the Wellcome Trust in the early 1990s by Virginia Berridge and Philip Strong, Co-directors of the AIDS Social History Programme at the London School of Hygiene and Tropical Medicine. For a discussion of the changing historical perspective on AIDS, see for example, V. Berridge, 'Introduction: AIDS and Contemporary History', p.4.

<sup>46</sup> J. M. Stanton, 'What shapes vaccine policy? The case of hepatitis B in the UK', *Social History of Medicine*, 7, 3, 1994, pp.427-46.

<sup>47</sup> *ibid.*

<sup>48</sup> J. M. Stanton, 'Health Policy and Medical Research: Hepatitis B in the UK since the 1940s', p.239.

<sup>49</sup> *ibid.*, p.267.

screening and thereby potential identification as a hepatitis B carrier at the forefront of the policy agenda.<sup>50</sup> In the early 1970s, during fatal outbreaks of hepatitis B in UK renal dialysis units, staff screening and exclusion of carriers from high risk patient areas had been seen as a means of controlling infection. Nevertheless, Stanton argued that ‘there was a liberal consensus against screening for any but a very small group of workers’, and that this stance influenced policy in the 1980s, after a vaccine was introduced.<sup>51</sup> Similarly, in New Zealand, as this study will show, the balance achieved in the pre-vaccine era between the rights of health care workers and the public health interest had some bearing on workplace policies in the 1980s.

The rights of health care workers to decline hepatitis B screening and immunisation came under renewed scrutiny in the 1990s. This was in part the result of public fears over the transmission of AIDS from infected health care workers to patients. Stanton concluded that several cases of hepatitis B transmission from surgeons to patients reported in the UK in the early 1990s had a powerful influence on policy makers, and that these cases added impetus to the introduction of radical policy changes.<sup>52</sup> In doing so, she illustrated the political nature of the policy process, and the importance of the social and cultural context in which health policy is made. This history, which draws on Stanton’s analysis, examines the response of the New Zealand Department (Ministry) of Health to the changes made to occupational policies in both the UK and the US in the 1990s to reduce the risks of hepatitis B transmission from infected health care workers to patients.

Within New Zealand there has been limited historical interest in hepatitis B. Vivien Edwards’ 2007 history of the New Zealand Hepatitis Foundation provided a detailed chronological record of the efforts of its founder and first director, Alexander Milne, and his supporters, to pressure successive governments to introduce universal childhood hepatitis B immunisation and population-based hepatitis B screening between the late

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<sup>50</sup> J. M. Stanton, ‘What shapes vaccine policy? The case of hepatitis B in the UK’, p.445.

<sup>51</sup> *ibid.*

<sup>52</sup> Stanton, ‘Health Policy and Medical Research: Hepatitis B in the UK since the 1940s’, p.263.

1970s and 2002. Although this was a careful and thorough account, Edwards paid little attention to the social and political issues underpinning events.<sup>53</sup>

By contrast, Alison Day located the conflict that evolved between Milne and the Health Department within the wider social context of the responses to child immunisation policy in New Zealand in the 1980s.<sup>54</sup> Day's 2008 PhD thesis identified a range of possible reasons for the Health Department's reluctance to respond to Milne's campaign for a childhood hepatitis B immunisation programme: its reliance on WHO recommendations on vaccine policy, the lack of epidemiological data to substantiate Milne's findings, and his lowly status as a laboratory technician were all contributory factors. In her view, however, the Department's response also pointed to a tendency to be 'very protracted in updating its ideas' which had been evident in its approach to earlier vaccines.<sup>55</sup> This study builds on Day's interpretation in its discussion of the social and political dynamics that shaped New Zealand's hepatitis B immunisation policies.

This case study of government policy for hepatitis B in New Zealand contributes to a relatively neglected area of history, both within New Zealand and internationally. While it focuses on the unique features of New Zealand's hepatitis B story, it adds to the wider historiography of hepatitis B and relates New Zealand's policy responses to those of other countries, in particular the UK and the US.

### **Historical studies of screening**

This thesis considers the introduction of, and debates around, screening for hepatitis B in New Zealand. Screening, as a public health measure in general, has attracted little attention from historians. A common focus of the historical studies has been the dichotomy between the sweeping claims made for population-based screening from the 1940s onwards, and the potential costs and harms of screening in practice, first brought to light by medical academics in the 1960s.

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<sup>53</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*.

<sup>54</sup> A. S. Day, 'Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920-90'.

<sup>55</sup> *ibid.*, p.223.

Published in 1978, Stanley Reiser's article tracing 'The emergence of the concept of screening for disease', explored the gradual disillusionment with the claims made by screening enthusiasts.<sup>56</sup> Reiser identified the issues raised by early critics of screening: the number of false-positive tests encountered in mass screening, the anxiety and unnecessary intervention they engendered, the economic costs of population-wide screening versus other preventive health measures, and the difficulties of assessing the significance of a health problem if a screening programme was introduced prematurely.<sup>57</sup> These concerns, also explored by Anne-Marie Foltz and Jennifer Kelsey in 1978 in a comparative study of cervical screening policies in the US, the UK, and Canada, were echoed by the Health Department and its advisers during the hepatitis B screening debates in New Zealand.<sup>58</sup>

In the 1980s, pressure to introduce targeted screening programmes for AIDS in many Western countries raised the spectre of compulsory screening and punitive public health measures based primarily on the results of laboratory tests.<sup>59</sup> Bridget Towers' 1993 essay, which arose from her appraisal of contemporary AIDS policies, examined four screening programmes introduced in the UK during the 1940s and early 1950s.<sup>60</sup> Towers, who questioned the assumptions that were made about the objectivity of the screening tests that were used, concluded that policy makers had limited understanding of the subjective interpretation of test results, and a narrow view of the economic and personal costs of screening, including the stigmatisation and anxiety experienced by people subjected to

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<sup>56</sup> S. J. Reiser, 'The emergence of the concept for screening for disease', *Health and Society*, 56, 4, 1978, pp.403-25.

<sup>57</sup> Among the most prominent early critics of screening identified by Reiser was Thomas McKeown, Professor of Social Medicine at the University of Birmingham, England. See for example, T. McKeown, ed., *Screening in Medical Care; Reviewing the Evidence, a Collection of Essays*, London, 1968. McKeown later became renowned for his work arguing that major medical improvements in the 19<sup>th</sup> and 20<sup>th</sup> centuries were the result of improved nutrition, sanitation, and housing, rather than 'triumphalist' medical progress.

<sup>58</sup> A. Foltz, J. Kelsey, 'The annual Pap test: A dubious policy success', *Health and Society*, 56, 4, 1978, pp.426-62.

<sup>59</sup> See, for example, V. Berridge, *AIDS in the UK: The Making of Policy, 1981-1994*, Oxford, 1996, for a discussion of the AIDS screening debate in the UK. For a discussion of the extreme proposals for AIDS screening put forward in the US and Australia in the mid-1980s see, for example, A. M. Brandt, 'AIDS: From social history to social policy', in E. Fee and D. M. Fox, *AIDS: The Burdens of History*, pp.147-71, and P. Sendziuk, *Learning to Trust: Australian Responses to AIDS*, Sydney, 2003.

<sup>60</sup> B. Towers, 'Historical perspectives on screening', in V. Berridge and P. Strong, *AIDS and Contemporary History*, pp.55-73.

screening tests. From a broader structural perspective, she asserted that health professionals used screening programmes as a means of establishing or retaining ‘territorial domains’ in contested areas of medicine.<sup>61</sup>

All of these issues, particularly the last, resonate with the New Zealand experience. This study will show that in political debates over the introduction of the population-based hepatitis B screening programme in the mid-1990s, Alexander Milne claimed that the Hepatitis Foundation was uniquely qualified to deliver this service on the basis of the expertise it had gained in screening ‘high risk’ school children. His arguments proved persuasive to politicians, if not to public health officials. On the other hand, the Health Department and its advisers expressed doubts over the cost effectiveness of population-based hepatitis B screening, and pointed to the potential stigmatisation of hepatitis B carriers identified by a screening programme.

In 2008 and 2009, Linda Bryder contributed to the historiography of screening in an article and a book, in which she explained how population-based cervical screening became widely accepted from the 1940s as an effective preventive health intervention. This was despite ongoing criticism from leading gynaecologists and epidemiologists, and scientific uncertainties around the treatment of cervical lesions.<sup>62</sup> Bryder, who argued that policy relating to cervical screening was influenced by professional agendas, political and social issues, commercial interests, and the mass media, concluded that ‘factors beyond science have impinged on policy making in public health interventions, and ... policy decisions do not necessarily flow directly from epidemiological or scientific evidence’.<sup>63</sup> The influence of factors other than epidemiological research on the development of hepatitis B policy is a recurring theme that is expanded on throughout this thesis.

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<sup>61</sup> *ibid.*, p.70.

<sup>62</sup> L. Bryder, ‘Debates about cervical screening: an historical overview’, *Journal of Epidemiology and Community Health*, 62, 2008, pp.284-7; see also, L. Bryder, *A History of the ‘Unfortunate Experiment’ at National Women’s Hospital*, Auckland, 2009, pp.89-107.

<sup>63</sup> L. Bryder, ‘Debates about cervical screening: an historical overview’, p.287.

Deborah Dunsford's 2007 PhD thesis examined New Zealand's mass X-ray campaign against tuberculosis, which was introduced in the 1950s, and which operated for nearly 30 years.<sup>64</sup> Dunsford concluded that the value of the campaign was 'largely symbolic', pointing to the economic and social costs of introducing screening programmes based on overly optimistic assumptions of benefit. She linked the enthusiastic public response to mass screening in the 1950s to the 'confidence in technology and medical science of the day'.<sup>65</sup> Yet despite a growing mistrust of science and medicine in the 1970s and 1980s, a strong belief in the inherent value of screening persisted in New Zealand.<sup>66</sup> In the mid-1990s, New Zealand politicians proved highly receptive to the notion that a national hepatitis B screening programme would bring unequivocal benefits for hepatitis B carriers, particularly those in the Maori community.

In taking up the story of population-based hepatitis B screening in New Zealand in the 1990s, this thesis examines the controversy that developed over its pros and cons between screening advocates and their supporters, and health officials and their advisors. It builds on earlier studies which concluded that from the 1940s onwards, population-based screening programmes were often based on unrealistic expectations of benefit, and that deeply embedded beliefs about the value of screening were an important influence on screening policy decisions.

### **The history of immunisation**

The introduction of hepatitis B immunisation is another important subject of this study. Early histories of immunisation from the 1950s and 1960s celebrated the works of 'great men', and the success of esteemed institutions in developing vaccines that dramatically reduced the incidence of infectious diseases, rather than exploring the broader social

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<sup>64</sup> D. A. Dunsford, 'Seeking the prize of eradication: a social history of tuberculosis in New Zealand from World War Two to the 1970s', PhD thesis, University of Auckland, 2008.

<sup>65</sup> *ibid.*, p.ii.

<sup>66</sup> See, for example, a recent article in the *NZ Listener* which challenges the widespread assumption that screening always brings public health benefits. R. Nichol, 'Screening meemies: Are programmes that screen for diseases all they're cracked up to be?', *NZ Listener*, 13 February 2010, pp.18-22.



context within which these events took place.<sup>67</sup> In the 1970s immunisation was increasingly included as a component of the history of individual diseases such as diphtheria and polio; however, it was not until the 1980s that historians began to examine the development of immunisation policies, and to explore the various factors that impinged on, and influenced, policy decisions.<sup>68</sup>

Historical studies on national responses to individual vaccines inform this thesis, which considers the factors that shaped the formation of hepatitis B immunisation policy from the registration of the vaccine in New Zealand in late 1982. Jane Lewis' 1986 study comparing Canadian and British approaches to diphtheria vaccine from 1914 to 1945 revealed that despite being recognised as a major problem by two countries with similar patterns of health provision, the introduction of the vaccine proceeded at distinctly different rates. Scientific developments did not necessarily drive policy; as with hepatitis B, the cost of the vaccine was a key factor in policy decisions.<sup>69</sup> In a 1999 article, Linda Bryder also pointed to a wide divergence in the Scandinavian, British and American responses to the use of BCG (Bacillus Calmette-Guerin) vaccine.<sup>70</sup> These differences, she argued, were not derived from the 'pure' facts of science. Rather, scientific research was conducted and interpreted within varying social and ideological frameworks and health systems that produced markedly different approaches to vaccination policy.<sup>71</sup> Ulrike Lindner and Stuart Blume's 2006 article examining the adoption of polio vaccine in the

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<sup>67</sup> Henry Parish's classic *A History of Immunization*, published in 1965, for example, focussed on vaccine development and the 'heroic' scientists who worked to 'conquer' infectious disease. H. J. Parish, *A History of Immunization*, Edinburgh, 1965. Similarly, in New Zealand, Francis Maclean's history of the Health Department published in 1964, discussed government responses to specific diseases within the framework of the achievements of individual doctors and departmental administrators. F. S. Maclean, *Challenge for Health: A History of Public Health in New Zealand*, Wellington, 1964.

<sup>68</sup> Despite a shift in emphasis in the 1970s, the 'heroic' view of vaccine development still held. See for example, John Paul's 1971 *A History of Poliomyelitis*, which provided a detailed record of the development of the polio vaccine in the US and the 'almost agonizing efforts by individual scientists that worked to ... contribute ... to the ultimate defeat of the disease'. J. R. Paul, *A History of Poliomyelitis*, New Haven, 1971, p.xiv. Nor was that the last history to celebrate 'great men' of science and medicine; Paul Offit's 2007 book tracing the life and achievements of medical scientist Maurice Hilleman, who developed the first hepatitis B vaccine, had a distinctly 'heroic' flavour. P. A. Offit, *Vaccinated: One Man's Quest to Defeat the World's Deadliest Diseases*, New York, 2007.

<sup>69</sup> J. Lewis, 'The prevention of diphtheria in Canada and Britain 1914-1945', *Journal of Social History*, 20, 1986, pp.163-76.

<sup>70</sup> L. Bryder, "'We shall not find salvation in inoculation": BCG vaccination in Scandinavia, Britain and the USA, 1921-1960', *Social Science and Medicine*, 49, 1999, p.1157-67.

<sup>71</sup> *ibid.*, pp.1157-8.

UK, the Netherlands, and Germany drew similar conclusions: scientific and epidemiological research was not the chief determinant of immunisation policy.<sup>72</sup>

As this study shows, public and political perceptions of the severity of a disease contribute to the priority, or lack of priority, given to immunisation policies. Hepatitis B differs significantly from other vaccine-preventable diseases that have attracted considerable historical attention. For instance, it has never acquired the distinctive identity of ‘paralytic’ poliomyelitis, which made such a powerful impression in Western societies in the first half of the twentieth century. Christopher Ruttly’s 1995 PhD thesis, which explored the response of Canadian governments to polio between 1927 and 1962, argued that it was polio’s striking physical effects rather than its epidemiological importance which attracted policy attention.<sup>73</sup> Similarly, Alison Day concluded that in New Zealand the dread of polio was so intense that in spite of the infamous 1955 Cutter Incident immunisation programmes attracted strong public support.<sup>74</sup> This study explores the public and political response to a largely invisible disease around which health activists created a sense of ‘emotional urgency’ to rally support for a state-funded immunisation programme.<sup>75</sup> Their public relations strategy, which was criticised for provoking public anxiety and panic, nevertheless proved successful in pushing hepatitis B up the health policy agenda.<sup>76</sup> In doing so, it revealed the political nature of the policy making process.

In the late 1980s, successive policies which expanded the scope of state-funded hepatitis B immunisation had variable success in reaching New Zealand children. The low uptake

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<sup>72</sup> U. Lindner, S. S. Blume, ‘Vaccine innovation and adoption: Polio vaccination in the UK, the Netherlands and West Germany, 1955-1965’, *Medical History*, 50, 2006, pp.425-46.

<sup>73</sup> C. J. Ruttly, ‘Do Something! ... Do Anything! Poliomyelitis in Canada 1927-1962, PhD thesis, University of Toronto, 1995, p.381.

<sup>74</sup> In the US in 1955, over 200 people were paralysed and ten people died after receiving contaminated vaccine prepared by the Cutter Laboratories. A. S. Day, ‘Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920-90’, 2008, pp.123-164; A.S. Day, ‘An American Tragedy. The Cutter Incident and its implications for the Salk polio vaccine in New Zealand, 1955-1960’, *Health and History*, 11, 2, 2009, p.58.

<sup>75</sup> This was a term used by Charles Rosenberg to describe one of the defining characteristics of an epidemic. C. E. Rosenberg, ‘What is an epidemic? AIDS in historical perspective’, p.7.

<sup>76</sup> ‘Concern, verging on panic’, *Bay of Plenty Times*, 5 July 1985; ‘Bassett assails hepatitis campaign’, *Dominion*, 5 July 1985.

of the hepatitis B vaccine among Maori children, in particular, forms a recurrent theme in this thesis. Others have explored the history of infant and child health policy for Maori and European New Zealanders. For instance, in his 1999 book on Maori health development from 1900 to 1920, Raeburn Lange discussed reasons for the high rates of infant mortality in Maori communities compared with the rates in the Pakeha population.<sup>77</sup> The high mortality rates among Maori, he suggested, were not only an indication of a 'limited utilisation of health facilities [but were a reflection] of the low overall standard of Maori health'.<sup>78</sup> However, as Linda Bryder explained in a 2001 article which examined the provision of infant welfare services and Maori from 1907 to 1960, such health facilities as were available for Maori were over-stretched and under funded.<sup>79</sup> The majority of Maori babies and preschoolers were followed up by government-funded district (later public health) nurses who were required to provide health care to whole communities, while the majority of European infants came under the care of Plunket Society nurses, whose sole focus was women and their babies.<sup>80</sup>

Bryder concluded that 'during the first half of the twentieth century a dual system evolved in infant care which left Maori disadvantaged'.<sup>81</sup> Even though public health nurses were allowed to give most infant and childhood immunisations from the mid-1940s, immunisation rates are likely to have been affected by this 'segregated' system.<sup>82</sup> Bryder's 2003 history of the Plunket Society described the important role taken by Plunket nurses in 'encouraging' Pakeha mothers to immunise their babies, and Day's 2008 thesis confirmed Plunket's key position in the delivery of immunisation policies.<sup>83</sup>

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<sup>77</sup> R. Lange, *May the People Live: A History of Maori Health Development 1900-1920*, Auckland, 1999.

<sup>78</sup> *ibid.*, pp.33-4.

<sup>79</sup> L. Bryder, 'New Zealand's infant welfare services and Maori, 1907-60', *Health and History*, 3, 1, 2001, pp.65-86. The Plunket Society was founded in 1907 as a voluntary organisation to 'help the mothers and save the babies'. The society received an annual grant from the government to fund most of its activities, but the remainder was made up by donations from the public.

<sup>80</sup> *ibid.*

<sup>81</sup> *ibid.*, p.86.

<sup>82</sup> L. Bryder, *A Voice for Mothers: The Plunket Society and Infant Welfare 1907-2000*, Auckland, 2003, p.181.

<sup>83</sup> *ibid.*; A. S. Day, 'Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920-90', pp.60-5. As Day explained, concerns over the health of preschool children led to an agreement between the Health Department and Plunket in 1940 to use their rooms to examine preschoolers and offer

While it is not possible to assess the longterm effects of this divided system of infant welfare on ethnic discrepancies in infant and childhood immunisation rates, these studies nevertheless provided important background for this history.

In the late 1980s, New Zealand's hepatitis B immunisation policy expanded to include all infants and preschool children; however, the Health Department was ill-prepared for changing parental attitudes towards childhood immunisation. In his 1995 history of the Health Department, Derek Dow attributed its difficulties in reaching projected national immunisation targets to growing parental complacency towards the threat of infectious diseases.<sup>84</sup> Day concurred, adding that the 'the decline in infectious diseases [overall] ... meant parents began to place more emphasis on the risks of immunisation than the benefits'.<sup>85</sup>

This thesis develops Day's analysis by considering parental concerns over the safety of the hepatitis B vaccine in the context of the consumer movement in health, which was exemplified by growing expectations that the Health Department would provide adequate information when it introduced new vaccines.<sup>86</sup> Furthermore, it builds on previous studies that have explored the influence of factors other than research findings on the formulation of immunisation policies.

### **Health policy history**

While there has been significant historical interest in the social, economic, political, and professional influences on health policy from the mid-nineteenth to the mid-twentieth century, less attention has been paid to health policy developed in recent decades. Among the historians who have taken a particular interest in investigating health policy in the second half of the twentieth century has been Virginia Berridge, whose work on areas of

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immunisations. This arrangement was more likely to improve the health of Pakeha than Maori children, who were largely excluded from Plunket services until the 1960s.

<sup>84</sup> D. A. Dow, *Safeguarding the Public Health: A History of the New Zealand Department of Health*, pp.224-5.

<sup>85</sup> A. S. Day, 'Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920-90', p.299.

<sup>86</sup> See, for example, F. Macdonald, 'Meningitis: Campaign goes astray', *NZ Listener*, 29 August 1987, pp.16-8.

contemporary policy significance, including AIDS and the science/policy relationship, proved particularly useful for this thesis.

In her 1996 book on the making of AIDS policy in the UK, Berridge described four consecutive 'phases of response' by UK policy makers from the early 1980s, which corresponded with the ways in which New Zealand health officials and politicians reacted to the threat of a potential AIDS epidemic.<sup>87</sup> In 1986, the widespread belief in the UK that 'a high level national emergency ... a national crisis on a par ... with the Second World War' was about to unfold, was echoed in New Zealand, where marshalling the country's resources to prepare for an AIDS crisis took priority over 'minor' problems such as hepatitis B, and indeed, over almost all other public health matters.<sup>88</sup> Without Berridge's interpretation of events, the intensity of the local response would have been more difficult to comprehend, particularly as the actual numbers of AIDS cases in New Zealand, as in the UK, lagged well behind those of comparable Western countries such as the US and Australia.<sup>89</sup>

In a 1996 article co-authored with Betsy Thom, Berridge illuminated the dynamics behind the 'research-policy relationship', an area of special interest for this study.<sup>90</sup> Berridge and Thom 'discount[ed] the notion of a rational relationship' between the two, concluding that the relationship is not dependent on 'scientific facts' but on the 'policy contexts and historical situations in which they operate'.<sup>91</sup> Further, they pointed to the power of medical civil servants who provided 'crucial "gateways" to policy influence' through their relationships with researchers, or with medical expertise in the formulation of drug and alcohol policy in the UK.<sup>92</sup> In an interesting twist, in the case of hepatitis B policy in New Zealand in the mid-1980s, this study will argue that medical officials in the

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<sup>87</sup> V. Berridge, *AIDS in the UK: The Making of Policy, 1981-1994*, p.6.

<sup>88</sup> *ibid.*, p.7. For the New Zealand response, see for example, *AJHR*, 1987, E.10, pp.3-4, in which Dr George Salmond, the Director-General of Health, described AIDS as one of two major issues to 'dominate the health scene ... [which will] Tax us all'.

<sup>89</sup> See Chapters Five and Nine for a discussion of comparative numbers of AIDS cases in these countries.

<sup>90</sup> V. Berridge, B. Thom, 'Research and policy: what determines the relationship?', *Policy Studies*, 17, 1, 1996, p.30.

<sup>91</sup> *ibid.*, p.31.

<sup>92</sup> *ibid.*

Health Department acted as ‘gatekeepers’ rather than ‘gateways’ as a result of their views on the relatively minor importance of hepatitis B as a public health problem.

Berridge built on this earlier analysis with Jennifer Stanton in the introduction to a special issue of *Social Science and Medicine* in 1999, in which they identified central concepts and themes in the relationship between research and policy making in health and medicine. They emphasised the importance of cross-national variation in responses to scientific research, the primacy of politics over science, and the international dimension to scientific legitimacy, all of which have relevance for this history of hepatitis B.<sup>93</sup>

In 2005, Berridge edited a collection of historical studies which examined aspects of the relationship between science and policy in the UK post-World War Two.<sup>94</sup> None of the chapters in this volume addressed the specific policy areas explored in this study; however, they contributed useful links and insights. Betsy Thom’s analysis of the networks between players in the alcohol policy ‘game’, in which ‘science is the football – essential, but only a part of the bigger spectacle’, Luc Berlivet’s discussion on the origins and influence of risk factor epidemiology on health policy, and Berridge’s own chapter describing the emergence of a ‘new style of media-conscious health activism’ in the 1970s, have all added to this history of hepatitis B policy in New Zealand.<sup>95</sup>

In the US, as Charles Rosenberg observed in 2006, the history of ‘recent [health] policy ... constitutes a relatively neglected area for research’.<sup>96</sup> Nor is the available analysis necessarily useful; for instance Daniel Fox’s 1993 book exploring the ‘failure and future of American health policy’ from 1900 to the early 1990s derived from the unique features

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<sup>93</sup> V. Berridge, J. Stanton, ‘Science and policy: historical insights’, *Social Science and Medicine*, special historical issue: Science Speaks to Policy, 49, 9, 1999, pp.1133-8.

<sup>94</sup> V. Berridge, *Making Health Policy: Networks in Research and Policy after 1945*.

<sup>95</sup> B. Thom, ‘Who Makes Alcohol Policy?: Science and Policy Networks 1950-2000’, pp.75-100; L. Berlivet, “‘Association or Caution?’ The Debate on the Scientific Status of Risk Factor”, pp.39-74; V. Berridge, ‘Issue Network versus Producer Network? ASH, the Tobacco Products Research Trust and UK Smoking Policy’, pp.101-24, in V. Berridge, *Making Health Policy: Networks in Research and Policy after 1945*.

<sup>96</sup> C. E. Rosenberg, ‘Anticipated Consequences: Historians, History, and Health Policy’, in R. A. Stevens, C. E. Rosenberg, L. R. Burns, eds, *Putting the Past Back in: History and Health Policy in the United States*, New Brunswick, 2006, p.13.

and direction of the US health system.<sup>97</sup> In spite of these differences, however, Rosenberg's 2006 essay on the 'seemingly meandering history of American health policy' uncovered familiar contradictions. His eloquent description of the '[dis]orderly' reality of health policy making in the US could equally have applied to the contested nature of hepatitis B policies in New Zealand: 'less a coherent package of ideas and logically related practices, than a layered conglomerate of stale-mated battles ... [and] negotiated cease-fires than a self-conscious commitment to data-sanctioned goals'.<sup>98</sup>

There have been few academic histories of New Zealand health policy in the late twentieth century, with the notable exceptions of Derek Dow's 1995 history of the Health Department, Alison Day's 2008 study of government policy for immunisation, and Linda Bryder's 2009 work on the development of population-based cervical screening policy. As already mentioned, this study builds on these works. In addition, Lisa Ferguson's 1997 MA thesis, which explored the development of marae-based initiatives to improve Maori health within the Tainui iwi from 1970 to 1995, traced increasing Maori autonomy in health provision as the self determination movement gained momentum in the 1980s and early 1990s.<sup>99</sup> Further, in a 2008 essay, Bryder considered the implications of government policies for Maori health up to and including early 2000.<sup>100</sup> Her analysis of the furore over the 'closing the gaps' policy initiatives introduced in 2000, which revealed the political sensitivities of ethnically-targeted health policies, provided useful insights into the controversy that arose as a result of the hepatitis B screening programme that was implemented between 1999 and 2002.<sup>101</sup>

Others have considered recent health policy within broader social policy histories of New Zealand, which have examined health alongside education, housing, and social

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<sup>97</sup> D. M. Fox, *Power and Illness: The Failure and Future of American Health Policy*, Berkeley, 1993.

<sup>98</sup> C. E. Rosenberg, 'Anticipated Consequences: Historians, History, and Health Policy', p.13.

<sup>99</sup> L. A. Ferguson, 'Marae-Based Health Initiatives within the Tainui Iwi from 1970-1995', MA thesis, University of Auckland, 1997, p.63.

<sup>100</sup> L. Bryder, 'Health Citizenship and "Closing the Gaps": Maori and Health Policy', in A. Andresen, T. Grønlie, W. Hubbard, T. Rymin and S. A. Skålevåg, eds, *Citizens, Courtrooms, Crossings*, Bergen, 2008, pp.51-61.

<sup>101</sup> *ibid.*, pp.57-8.

welfare.<sup>102</sup> However, while these studies provided useful background in terms of key periods of policy change and major shifts in the relationship between the state and the individual and the state and Maori since the 1970s, they lacked specific detail on the factors that influenced health policies during the late twentieth century.

Writers from a range of other academic disciplines have tackled issues that resonate with the general theme of this thesis, that is, the ways in which social, economic and political forces, rather than the apparently objective findings of research or ‘pure’ science, have shaped hepatitis B policy and influenced the ways in which it was implemented. For example, contemporary writings by Maori into the state of Maori health inform this study. In the 1980s, Dr Eru Pomare, a well-respected Maori physician and public health researcher, produced two reports which confirmed the poor health status of Maori.<sup>103</sup> Pomare became a leading proponent of hepatitis B immunisation in 1985 after conducting a ministerial review of the community-funded immunisation programme in the Eastern Bay of Plenty.<sup>104</sup> Like his contemporary Mason Durie, a psychiatrist and highly regarded Maori leader, Pomare advocated Maori control of Maori health.<sup>105</sup> Durie’s influential writings on Maori health were a valuable resource for this thesis, which considers the perceived health needs and priorities of Maori to be of central importance in the development of hepatitis B policy.

This thesis also draws on more general sociological studies of health policy in the late twentieth-century. A common feature of these studies has been the focus on the effects of the health sector restructuring of the late 1980s and the radical health reforms of the early

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<sup>102</sup> See, for example, G. W. Rice, ‘A Revolution in Social Policy, 1981-1991, in G. W. Rice, ed., *The Oxford History of New Zealand*, 2<sup>nd</sup> edn, pp.482-97; M. Belgrave, ‘Needs and the State: Evolving Social Policy in New Zealand History’, in B. Dalley and M. Tennant, eds, *Past Judgement: Social Policy in New Zealand History*, Dunedin, 2004, pp.23-38.

<sup>103</sup> E. W. Pomare, *Maori Standards of Health: A Study of the 20 Year Period 1955-1975, Special Report Series No 7*, Wellington, 1980; E. W. Pomare and G. M. de Boer, *Hauora: Maori Standards of Health: A Study of the Years 1970-1984, Special Report Series No 78*.

<sup>104</sup> E. W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, Wellington, 1985.

<sup>105</sup> See, for example, M. Durie, ‘The Treaty of Waitangi and health care’, NZMJ, 102, 14 June 1989, pp.283-5; M. Durie, *Whaiora: Maori Health Development*, Auckland, 1994, p.1; M. Durie, *Mauri Ora: The Dynamics of Maori Health*, Melbourne, 2001.



1990s, which provided a counterpoint to the extended period of relative stability that preceded them.<sup>106</sup> Political scientists Tim Tenbenschel and Robin Gauld considered the changing influences on health policy makers from the 1970s onwards, pointing to the dominance of medical experts prior to the 1980s, and the market-led approach to health policy that took hold from the mid-1980s to the late 1990s.<sup>107</sup> Further, in his 2009 book on the ‘continuing saga’ of the New Zealand health reforms, Gauld drew attention to the role of individual health ministers as policy ‘drivers’.<sup>108</sup> In doing so, he shed light on the vagaries of hepatitis B immunisation policy in the late 1980s.<sup>109</sup>

For the purposes of this study, essays on the fundamentals of policy development clarified the policy making process. While political scientist Robert Blank considered the role of the public in setting the health policy agenda, former Director-General of Health George Salmond (1986–1991) and former Deputy Director-General (Administrative) John Martin (1981–1987) examined the ‘messy reality’ of health policy making.<sup>110</sup> Salmond, in particular, was a key player in the formulation of hepatitis B policy during the 1980s, giving this discussion of the health policy process an even greater relevance.

Earlier works also provided useful background for this study. Political scientists A. D. Robinson and Stephen Levine, for example, considered the ways in which interest groups, including single-issue health lobbyists, applied pressure on governments to adopt specific policies.<sup>111</sup> In addition, Levine identified the importance of the annual budget as a political document that reflected both the priorities of the government, and the social and cultural values of the electorate.<sup>112</sup> The implications of the budgetary process were

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<sup>106</sup> See, for example, P. Barnett and R. Barnett, ‘Reform and Change in Health Service Provision’, in K. Dew and P. Davis, eds, *Health and Society in Aotearoa New Zealand*, 2<sup>nd</sup> edn, Auckland, 2005, pp.178-93; P. Davis and T. Ashton, ‘Introduction’, pp.1-20, and T. Ashton, ‘The Influence of Economic Theory’, pp.107-26, in P. Davis and T. Ashton, eds, *Health and Public Policy in New Zealand*, Auckland, 2001.

<sup>107</sup> *ibid.*, T. Tenbenschel and R. Gauld, ‘Models and Theories’, pp.24-43.

<sup>108</sup> R. Gauld, *Revolving Doors: New Zealand’s Health Reforms – the Continuing Saga*, p.63; p.74.

<sup>109</sup> *ibid.*, p.52.

<sup>110</sup> R. H. Blank, ‘Agenda Setting and Policy Context’, pp.144-58, and J. Martin and G. Salmond, ‘Policy Making: The Messy Reality’, in P. Davis and T. Ashton, *Health and Public Policy in New Zealand*, pp.44-61.

<sup>111</sup> A. D. Robinson, *Notes on New Zealand Politics*, Wellington, 1970; S. Levine, ed., *New Zealand Politics: a Reader*, Melbourne, 1975.

<sup>112</sup> *ibid.*, p.162.

explored more recently in former Health Minister Michael Bassett's 2008 memoir of the Fourth Labour Government.<sup>113</sup> By these accounts, the wide disparity between the funding allocation for AIDS-prevention and hepatitis B immunisation can be seen as a clear indication of the political priorities of the mid-1980s. This thesis builds on and contributes to these broader historical and sociological studies by providing an in-depth historical analysis of one particular health problem, hepatitis B.

### **Thesis sources, themes and structure**

My study of government policy for hepatitis B is based primarily on an examination of Health Department and Ministry of Health files relating to hepatitis B immunisation and screening held by Archives New Zealand in Auckland and Wellington, and by the Ministry of Health in Wellington. I also consulted the Health Department's Annual Reports and the New Zealand Parliamentary Debates, and accessed personal papers, such as the Michael Bassett papers, held at the Alexander Turnbull Library, Wellington.

Where archival collections were incomplete, private collections of official files were of great assistance. As health policy maker and historian Warwick Brunton explained, one feature of the 'cataclysmic' changes in the health services and public sector during the 1980s and early 1990s was staff reduction and turnover, which led to the 'considerable haemorrhaging of institutional memory' and inadvertent loss of official records.<sup>114</sup> Without access to privately held files, it would have been impossible to trace the activities of the Health Department Transfusion Advisory Committee, for instance.<sup>115</sup>

Journals published from the 1940s onwards were an additional source of primary material. The main journal used was the *New Zealand Medical Journal*, although a wide range of international journals was consulted. National newspapers were viewed to

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<sup>113</sup> M. Bassett, *Working with David: Inside the Lange Cabinet*, Auckland, 2008.

<sup>114</sup> W. Brunton, 'The Place of History in Health Policy-Making: A View from the Inside', in L. Bryder and D. A. Dow, eds, *New Countries and Old Medicine, Proceedings of an International Conference on the History of Medicine and Health*, Auckland, 1995, p.136.

<sup>115</sup> I am grateful to Professor Bruce Howie for allowing me to access his personal collection of Transfusion Advisory Committee (TAC) minutes from the mid-1960s to 1980, and to Dr James Faed for providing me with access to the TAC minutes from 1980.

assess coverage of key policy decisions. A private collection of news cuttings from Eastern Bay of Plenty newspapers proved useful in gauging media responses to community-funded hepatitis B immunisation initiatives.<sup>116</sup> The Television New Zealand (TVNZ) archives were a valuable source of documentary and current affairs programmes as were video recordings held by private individuals.

Oral interviews were the other major source of primary data for this thesis. Used extensively in recent decades to give voice to the lives of ‘ordinary people’ excluded from mainstream histories, oral history has had a parallel, if less prominent, focus on the lives of significant figures in areas such as politics, government, and research.<sup>117</sup> For the purposes of my research, the personal experiences and perceptions of people who participated in making hepatitis B policy were essential to understanding the context of official documents and the interplay of events. This does not imply that the memories of those who have made or influenced policy have more value than those who have experienced or witnessed its effects. Rather, as Anthony Seldon and Joanna Papworth explained in their book *By Word of Mouth: Élite Oral History*, ‘elite’ figures are of historical interest because of the position they held, or the influence they exerted on policy decisions, not because they are necessarily representative of a social group, gender, or class.<sup>118</sup>

In all I conducted thirty six oral interviews with politicians, public health officials, members of the official advisory committees on transfusion and infectious diseases, public health specialists, medical personnel, and laboratory scientists. Potential interviewees were identified through the membership lists of official committees and working parties, and by the snowball method, through personal referral. Ethics approval for oral interviews was gained from the Northern Region Ethics Committee. Consistent

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<sup>116</sup> I am also grateful to Alexander Milne for providing me with access to his collection of news cuttings on hepatitis B from national and regional newspapers from 1983 to 1987, and to papers and videos from his private collection relating to his activities promoting hepatitis B immunisation and screening.

<sup>117</sup> D. A. Ritchie, *Doing Oral History*, New York, 1995, cited in A. Green, ‘Oral History and History’, in A. Green and M. Hutching, *Remembering: Writing Oral History*, Auckland, 2004, p.4. Anthony Seldon and Joanna Papworth provide a useful summary of the development of ‘elite’ and ‘non-elite’ oral history in A. Seldon and J. Papworth, *By Word of Mouth: Élite Oral History*, London, 1983, pp.6-11.

<sup>118</sup> *ibid.*, preface; p.6.

with established oral history techniques, I transcribed the majority of these interviews to enable participants to review and, if necessary, correct the content to their satisfaction.<sup>119</sup> Personal contact was also made with twelve other people who had either been involved in international hepatitis B research and policy, or who had been involved in public health, child health, or blood transfusion in New Zealand between the late 1960s and the mid-2000s.

As hepatitis B was an area of health policy marked by controversy and divided opinion, I anticipated that the oral interviews would reveal a range of perspectives on the issues, events, and people that shaped policy decisions. I did not consider the wide variance in views as indicative of a weakness in oral history methodology; on the contrary, as Anna Green suggested, ‘the subjectivity of individual memory [can be] a positive resource for the study of history, not a liability’.<sup>120</sup> The challenge lay in connecting individual experience with the broader social, political and economic context of events, and in examining individual viewpoints in relation to the direction that policy took.<sup>121</sup>

The primary aim of the oral interviews was to capture individual recollections and insights into the events and influences surrounding policy decisions. Oral evidence provided a means of cross-referencing archival data, of developing lines of enquiry, and of gaining new perspectives on official documents. As I began the interviews, however, the additional benefits of oral history emerged. The interviews allowed me to consider the influence of unique personalities and characters, to make vital links between policy players that I might otherwise have missed, and to gain a deeper understanding of the influence of individuals on the policy making process. As Seldon and Papworth suggested, the opportunity to assess individual personalities is ‘one of the areas where

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<sup>119</sup> See for example, F. Good, ‘Voice, Ear & Text: Words, Meaning & Transcription’, in R. Perks and A. Thomson, eds, *The Oral History Reader*, 2<sup>nd</sup> edn, New York, 2006, pp.362-72.

<sup>120</sup> A. Green and M. Hutching, *Remembering: Writing Oral History*, p.2.

<sup>121</sup> *ibid.*, p.3. See also A. Portelli, ‘What Makes Oral History Different’, in R. Perks and A. Thomson, eds, *The Oral History Reader*, New York, 1998, pp.69-70. Portelli described memory as ‘not a passive depository of facts, but an active process of creation of meanings ... Oral sources are not objective. This of course applies to every source, though the holiness of writing often leads us to forget it’.

oral history can make its richest contribution'.<sup>122</sup> Furthermore, the information on personal relationships which does not get into official records can provide 'the clue to many key developments, all the harder to understand because such relationships may not only be complex but veiled to contemporaries ... How these relationships worked can be elucidated most effectively by oral evidence, often long after the events'.<sup>123</sup>

International influences on hepatitis B screening and immunisation policy, the role of individual players in policy making, the high cost of the hepatitis B vaccine, the marked ethnic differential in infection rates, the reluctance of the Health Department to act on hepatitis B, the conflicts between health activists and health officials, and the tensions between individual rights and the public health, are themes that reappear throughout my thesis. I have used a chronological approach to reflect the connection between successive technological developments, including the hepatitis B test in the early 1970s and the hepatitis B vaccine in the early 1980s, and the development of hepatitis B policy, to provide a clear sequence in the narrative flow of events.

Chapter Two considers the role taken by transfusion specialists in the introduction of hepatitis B screening in blood banks in the early 1970s. It draws attention to the tensions that developed between the Health Department and the transfusion services as more sensitive, efficient, and expensive screening tests became available over the 1970s.

Chapter Three examines policy responses to hepatitis B as an occupational hazard, and explores the growing international consensus on the management of hepatitis B infected health care workers during the 1970s. It asks why local prevalence data which suggested striking ethnic disparities in the prevalence of hepatitis B in New Zealand was ignored by Health Department officials, who focused almost entirely on the infection risks to health care workers.

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<sup>122</sup> A. Seldon and J. Papworth, *By Word of Mouth: Élite Oral History*, preface; p.38.

<sup>123</sup> *ibid.*, p.40.

Chapter Four, which covers the period from 1980 to 1985, considers the role of Alexander Milne in raising public and political awareness of the high prevalence of hepatitis B among New Zealand children. It asks two questions: why was the Health Department so reluctant to respond to widespread calls for state-funded hepatitis B immunisation for children, and how did fears of an impending AIDS epidemic impact on policy for hepatitis B?

Chapter Five considers the meteoric rise of hepatitis B as a political priority in 1987, an election year. Political expediency, rather than expert advice, is seen to drive developments in hepatitis B immunisation policy. Chapter Six examines the implementation of the preschool immunisation programme. The depth of the Health Department's commitment to improving Maori health standards comes under scrutiny, as does its decision to limit state-funded hepatitis B immunisation to babies and young children.

Chapter Seven explores the debates over the introduction of nationwide population-based hepatitis B screening, and highlights the impact of single-issue health advocacy and social and cultural values on screening policy. Chapter Eight examines the effects of radical restructuring of the health sector on the delivery of hepatitis B vaccine in the 1990s and beyond. It asks why hepatitis B immunisation rates in New Zealand languished, particularly among Maori and Pacific children, while comparable countries lifted their rates substantially. Chapter Nine returns to the theme of hepatitis B as an occupational hazard, and considers the changing balance between the rights of hepatitis B infected health care workers to privacy and job security, and the rights of patients to protection, from 1990 to 2005.

By investigating the social, political and economic factors that shaped policy decisions, this thesis aims to fill a gap in the New Zealand historiography relating to public health and social policy in the late twentieth century. In spite of its importance as an infectious disease, little has been written on the history of hepatitis B in New Zealand. This is

despite the fact that hepatitis B continues to be a serious illness in New Zealand.<sup>124</sup> This study also aims to contribute to the limited international historiography of the disease, and to the growing historical literature dealing with public health issues in the late twentieth century. In some respects, policy responses to hepatitis B in New Zealand will be seen to be unique to its particular culture and conditions, but in others, clear patterns will emerge that link New Zealand's experience to that of other Western countries, particularly the UK and the US.

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<sup>124</sup> 'In New Zealand, [hepatitis B] kills more people than any other vaccine preventable disease, except influenza'. Ministry of Health, *Immunisation Handbook 2006*, Wellington, 2006, p.126.





## CHAPTER TWO

### THE INTRODUCTION OF HEPATITIS B SCREENING IN NEW ZEALAND BLOOD BANKS

1970–1982

Early in 1971, the Auckland Blood Transfusion Service started routine screening of donor blood for the hepatitis B virus. Over the following year, blood bank laboratories throughout New Zealand introduced the screening test. Local transfusionists regarded this as a major achievement for the safety of the blood supply; since the 1940s, when ‘serum’ hepatitis was first recognised as a blood borne disease, it had been considered the most serious infectious complication of blood transfusion. The original hepatitis B test, developed by US researchers in the late 1960s, was slow and lacked sensitivity, but it represented the first real opportunity to reduce the risk of infection to transfusion recipients. New Zealand transfusion services were among the earliest to adopt routine hepatitis B screening; American and Australian blood banks began screening in late 1970, while transfusion centres around the UK started screening in 1972.<sup>1</sup>

In New Zealand, the Transfusion Advisory Committee (TAC), established in the early 1960s to advise the Minister of Health on transfusion-related matters, drove the screening agenda. The TAC, which comprised of medical specialists responsible for the country’s transfusion services, had no executive powers; nevertheless, it was highly influential in policy development at the national and local level. Even though the Health Department

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<sup>1</sup> For the introduction of hepatitis B screening in US blood banks, see for example, Division of Medical Sciences, *ad hoc* Committee on Hepatitis-Associated Antigen, statement concerning the use of hepatitis-associated antigen tests for donor screening in blood banks, reported at the 23<sup>rd</sup> annual meeting of the American Association of Blood Banks, 29 October 1970, cited in National Academy of Sciences, *Annual Report: Fiscal Year 1970-71*, Washington, 1974, pp.21-2. For hepatitis B screening in the Australian transfusion services, see for example, Y. E. Cossart, S. Kirsch, S. L. Ismay, ‘Post-transfusion hepatitis in Australia: Report of the Australian Red Cross Study’, *Lancet*, 319, 8265, 23 January 1982, pp.181-236, and the Australian Red Cross ‘Timeline’, online, nd, available at: [http://www.redcross.org.au/aboutus\\_history\\_timeline.htm](http://www.redcross.org.au/aboutus_history_timeline.htm) (15 February 2010). In the UK, some regional blood banks introduced hepatitis B screening earlier than others, but by 1972, universal screening of all blood donations had been introduced throughout the country. J. M. Stanton, ‘Health Policy and Medical Research: Hepatitis B in the UK since the 1940s’, p.150.

balked at the costs involved, once a test became available in the late 1960s, the TAC regarded routine hepatitis B screening of donated blood as an essential measure to reduce the prevalence of posttransfusion hepatitis. Committee members were determined that local transfusion recipients would receive the benefits of testing, and that New Zealand would keep abreast of internationally recognised transfusion practice.

As background to the introduction of hepatitis B screening in New Zealand, this chapter will begin by examining the role of the TAC in developing a coordinated approach to transfusion policy. It will then consider the threat posed to patients from contaminated blood, and the policies and procedures put in place to reduce the risks of posttransfusion hepatitis. The role of Dr John (later Sir John) Staveley, Director of the Auckland Blood Transfusion Service and a foundation member of the TAC, as a key advocate for the early introduction of hepatitis B testing will also be addressed. The pressure to adopt more sensitive testing methods during the 1970s will be considered in the context of international developments in screening technology, the dependence of New Zealand's transfusion services on Australian plasma processing facilities, and the funding constraints imposed by the Health Department. This chapter will also discuss other important outcomes of the screening policy, including the first epidemiological data on the prevalence of hepatitis B virus infection in New Zealand.

### **The Transfusion Advisory Committee (TAC)**

In May 1963, thirteen years after the New Zealand Society of Pathologists first proposed a nationally coordinated transfusion service, the TAC held its inaugural meeting in Wellington.<sup>2</sup> From its inception, the committee aimed to standardise transfusion policies and practices, and to develop a cooperative working relationship between transfusion regions.

Transfusion services in New Zealand evolved on the UK model, within the public health system. Each hospital board collected and stored blood from local donors, and prepared

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<sup>2</sup> J. B. Howie, 'A. B. Pearson Memorial Address', presented to the 40<sup>th</sup> Annual Meeting of the New Zealand Society of Pathologists, Wanaka, 24 May 1988, p.1, private papers, J. B. Howie.

its own intravenous solutions. In 1950, in recognition of the need for nationwide standards and more efficient use of blood donations, the New Zealand Society of Pathologists requested a meeting with the Health Department. When the meeting was convened in March 1951, members of the society presented detailed recommendations for a national blood transfusion organisation. Dr Claude Taylor, Director of the Hospitals Division, and Dr Duncan Cook, Director of the Division of Clinical Services, represented the Department, but transfusion was also of vital interest to a wide range of medical and military organisations: representatives of the Medical Superintendents Association, a member of the Royal Australasian College of Surgeons, and representatives from each of the Armed Forces were also present.<sup>3</sup> Yet despite the apparently urgent need to coordinate services and improve safety standards, the Health Department made no attempt to develop a national directive on transfusion policy. During the 1950s, public hospitals continued to provide localised transfusion services on an ad hoc basis.

There was no apparent explanation for the Department's reluctance to act on the concerns raised by local pathologists, or for the decision to seek trans-Tasman guidance on transfusion policy nearly a decade later. In 1960, departmental officials invited Professor R. J. Walsh, Director of the New South Wales Red Cross Transfusion Service, to give advice on the reorganisation of the New Zealand blood transfusion services.<sup>4</sup> Professor Bruce Howie, pathologist and haematologist responsible for transfusion at Dunedin Hospital from 1950 to 1980, later recalled that it was intensely frustrating to wait so long for the Health Department to respond:

We were well aware of the risks and the tragedies which could happen [in transfusion] ... [and] of the dangerous way in which [transfusion] was operating in some of the [hospital] boards. We were hot under the collar that it had taken ten years for anything to happen. We were delighted when they called the meeting in Auckland in 1960 ... [But] we didn't really know what

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<sup>3</sup> *ibid.*, pp.1-2. The Royal Australasian College of Surgeons (RACS) is responsible for the training and professional development of New Zealand and Australian surgeons. Approximately 90 per cent of New Zealand surgeons are Fellows of the College. RACS, 'About the College', online, nd, available at: <http://www.surgeons.org/Content/NavigationMenu/WhoWeAre/Regions/NZ/default.htm#office> (8 July 2009).

<sup>4</sup> J. B. Howie, 'A. B. Pearson Memorial Address', p.2.

it was all about until we got there to find an Australian advisor had been invited.<sup>5</sup>

Walsh recommended the formation of a transfusion advisory body, both to give advice on transfusion matters at a ministerial level and to promote uniformly high standards of transfusion throughout New Zealand. In March 1963, the TAC was duly appointed within the Hospitals Division of the Health Department. The five members of the committee were gazetted as Regional Transfusion Officers for five transfusion regions: Auckland, North Auckland and Waikato-Bay of Plenty, Dr J. M. ('Jock') Staveley; Palmerston North, Taranaki and Hawkes Bay, Dr T. H. Pullar; Wellington, Marlborough Sounds and Nelson, Dr M. McKellar; Canterbury and West Coast, Dr F. H. Gunz; Otago and Southland, Dr J. B. Howie.<sup>6</sup>

When the TAC was first appointed, Jock Staveley was the only member with specialist training in transfusion.<sup>7</sup> During World War Two, he had worked as a transfusion officer in the New Zealand Armed Forces, and he later recalled that 'having seen on such a scale what could be achieved by blood transfusion, my interest never wavered'.<sup>8</sup> In 1950, after returning to New Zealand from postgraduate study in London and Edinburgh, he was appointed as haematologist in charge of transfusion at Auckland Hospital's Central Laboratory, and later, from 1964 to 1976, as full-time Director of the Auckland Blood Transfusion Service.<sup>9</sup> The other members of the committee, who had also completed postgraduate study in the UK, were specialists in pathology or haematology with a strong clinical interest in the new treatments being developed for haemophiliacs and patients

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<sup>5</sup> J. B. Howie, interviewed by D. M. Jowitt, 9 November 2006.

<sup>6</sup> J. B. Howie, 'History of the Transfusion Advisory Committee', 14 May 1982, p.1, private papers, J. B. Howie.

<sup>7</sup> Howie described Staveley as 'the only "real" transfusionist' when the TAC was first formed. J. B. Howie, personal communication, 20 May 2007.

<sup>8</sup> T. Duder, 'Last Word: Pioneer became lifeblood of advancements in transfusion', *New Zealand Herald* (NZH), 27 May 2006.

<sup>9</sup> L. Bryder and D. A. Dow, *Banking on Blood: Auckland Regional Blood Services 1941-1991*, Auckland, 1991, p.18.

with diseases of the blood, such as leukaemia.<sup>10</sup> Like Staveley, they were keen to develop a coordinated national transfusion service, both to improve safety standards and to meet the rapidly growing demand for blood and blood products.<sup>11</sup>

The TAC met regularly from 1963. The five regional transfusion officers were more than ready to exert their collective influence to improve the uneven standard of transfusion practice in New Zealand, but there were limits to their authority within and beyond their individual hospital boards. According to Howie, this was defined by their training, experience, and the breadth of their clinical responsibilities. Funding ('the really important issue', Howie believed) for additional staff and equipment was only provided by the five boards: Auckland, Palmerston North, Wellington, Christchurch and Dunedin.<sup>12</sup> Furthermore, not all boards were equally supportive of the development of regional transfusion services. Nonetheless, the TAC undertook to review transfusion practice throughout New Zealand and to coordinate and standardise blood collection procedures, the criteria used to select donors, and minimal standards for accrediting donor blood for clinical use.<sup>13</sup>

As well as collecting whole blood for transfusion, the TAC developed a national programme for the production of plasma products. In 1963, the committee brought a proposal to the Health Department for the local production of freeze-dried plasma and cryoprecipitate, blood components used to treat haemophilia and other blood disorders. The Auckland Transfusion Service, which had the largest donor population, was chosen as the centre best suited for this purpose. Moreover, according to Howie, the service was more advanced than other centres as a result of 'the influence of Dr Staveley'.<sup>14</sup> In this

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<sup>10</sup> According to Dr James Faed, who became Regional Transfusion Officer for Otago in 1981, apart from Staveley, the other transfusionists held multiple roles: 'Jock Staveley will have been a key player as a full time transfusion person, as well as Bruce Howie who had a much more varied job as a haematologist here in Dunedin [and who] wasn't just in transfusion. He was employed by the university, so he was a half-time university, half-time hospital person, with responsibility for haematology and the transfusion laboratory.' J. M. Faed, interviewed by D. M. Jowitt, 8 November 2006.

<sup>11</sup> J. B. Howie, personal communication, 20 May 2007.

<sup>12</sup> J. B. Howie, interviewed by D. M. Jowitt, 9 November 2006.

<sup>13</sup> J. B. Howie, 'History of the Transfusion Advisory Committee', p.2.

<sup>14</sup> J. B. Howie, 'A. B. Pearson Memorial Address', p.5.

and other matters, the Department acquiesced, providing additional funding to equip the Auckland Blood Transfusion Service as the national plasma production centre for the other regions.<sup>15</sup> With this arrangement in place, the TAC was able to secure a trans-Tasman exchange of blood products, through an informal agreement with the Commonwealth Serum Laboratories (CSL) in Melbourne.<sup>16</sup>

From 1963, the Auckland Blood Transfusion Service sent CSL fresh plasma from regional blood banks around New Zealand for fractionation, and the production of albumin and immunoglobulin, which were then shipped back to the Auckland Blood Transfusion Service to distribute to the regional services. This cooperative approach meant that doctors around the country had access to specialist blood products for the newer, more aggressive therapies that increasingly characterised ‘modern’ medicine.<sup>17</sup> The TAC also made significant progress on standardising transfusion practice throughout the country. The first official criteria for donor selection and the technical aspects of blood collection were published in mid-1964, and the introduction of standard transfusion equipment enabled the safe exchange of blood and blood products between regions.<sup>18</sup>

Departmental officials did not oppose these policies; on the contrary, as Howie explained, ‘there was nobody sitting in the Health Department who thought they knew anything about transfusion’.<sup>19</sup> As the key advisors on transfusion matters, the TAC therefore had considerable influence. Dr John Boyd, Deputy-Director of the Department’s Hospitals Division, who chaired the TAC from the mid-1960s, played an important role in communicating its recommendations to senior health officials. Howie described Boyd as

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<sup>15</sup> The Health Department also provided extra funding to the Auckland Hospital Board for the purchase of fractionated blood products from CSL in Melbourne, so that they could be delivered to other boards at no charge. J. B. Howie, ‘History of the Transfusion Advisory Committee’, p.3.

<sup>16</sup> CSL was initially established in Melbourne in 1916 to produce serum and vaccines for the Australian armed forces. By the 1960s, it was producing a range of specialist blood products. CSL, ‘Our History’, online, nd, available at:

<http://www.csl.com.au/s1/cs/auhq/1187378853379/content/1187378853349/content.htm>

(3 June 2010).

<sup>17</sup> J. B. Howie, interviewed by Deborah Jowitt, 9 November 2006.

<sup>18</sup> Department of Health, *Criteria for Acceptance of a Voluntary Blood Donor, Requirements in Patient Identification and Minimum Standards of Technical Handling of Blood*, Wellington, 1964; J. B. Howie, ‘A. B. Pearson Memorial Address’, 1988, p.5.

<sup>19</sup> J. B. Howie, interviewed by D. M. Jowitt, 9 November 2006.

being ‘on the committee’s side’ and as ‘very, very important in our activities for a number of years’.<sup>20</sup> While Boyd acted as an ally within the Department, committee members were well-placed within their own hospitals and regions to advance their policy agenda, both as transfusion officers and as clinical specialists in haematology and pathology.

In summary, by the mid-1960s the TAC had established a coordinated transfusion service with greater capacity to meet the growing need for blood and blood products in New Zealand. Committee members, who combined clinical expertise with their knowledge of transfusion medicine, took the initiative in policy planning, development and delivery at both national and local levels.

### **Attempts to reduce the risks of posttransfusion hepatitis in the 1960s**

The 1960s saw the introduction of new surgical procedures and medical treatments, many of which used large quantities of blood, plasma, and specialised blood products. While there was great enthusiasm for these therapeutic measures among the medical community and the general public, blood banks were aware that recipients exposed to multiple transfusions were more likely to develop serum hepatitis.<sup>21</sup> Without a screening test to detect infectious blood, New Zealand blood banks, like those in the UK and US, used the limited means at their disposal to reduce the risk of infection.

In the early 1940s, during World War Two, serum hepatitis was recognised as a surprisingly common infectious complication of blood transfusion.<sup>22</sup> Medical nomenclature for the new disease, which varied from ‘homologous serum hepatitis’ to ‘posttransfusion hepatitis’, was changed in the late 1940s to hepatitis B, even though the

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<sup>20</sup> *ibid.*

<sup>21</sup> Serum is the clear liquid that can be separated from clotted blood. Serum differs from plasma, which is the liquid portion of unclotted blood and contains red and white blood cells and platelets.

<sup>22</sup> P. B. Beeson, ‘Jaundice occurring one to four months after transfusion of blood or plasma’, *JAMA*, 24 April 1943, pp.1332-4; P. E. Sartwell, ‘Infectious hepatitis in relation to blood transfusion’, *Bulletin of the U.S. Army Medical Department*, 7, January 1947, pp.90-100.

earlier terms continued to be used widely within the medical profession.<sup>23</sup> During the 1950s and early 1960s, despite intensive research, scientists were unable to identify a causative virus for the disease or to develop a means of preventing contaminated blood and plasma from entering the blood supply. As a consequence, serum hepatitis, which was potentially fatal, remained a serious hazard for transfusion recipients.

The prevalence of the disease was thought to be much higher than the number of cases that came to medical attention; at least five times as many sub-clinical infections were estimated to occur for every overt case of posttransfusion hepatitis.<sup>24</sup> Dr Graeme Woodfield, who was a medical registrar at Auckland Hospital in the early 1960s, explained that at that time it was considered normal to have at least half a dozen patients with serum hepatitis in the Infectious Diseases Unit: ‘We just regarded serum hepatitis as being one of the inevitable consequences of transfusion.’<sup>25</sup>

The 1960s was a notable period of expansion and innovation in New Zealand medicine. Transfusion was crucial to the pioneering work on open heart surgery in Auckland’s Green Lane Hospital, the development of intrauterine transfusion at National Women’s Hospital, hip replacements in orthopaedic surgery, and new approaches to treatment for haemophilia. Walter Wilson, who started as a trainee medical laboratory technologist with the Auckland Blood Transfusion Service in 1965, recalled the extensive use of blood and blood products during the late 1960s:

In those days ... we used twelve units of blood every morning to prime the [cardiac] bypass machine. Hip replacements and other major traumatic surgery were being developed and they were huge users of blood.

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<sup>23</sup> The use of the term ‘hepatitis B’ was first suggested in late 1947 by Fred MacCallum, a Canadian researcher with the Wellcome Bureau of Scientific Research who had been involved in studies on serum hepatitis since the late 1930s. Anon., ‘Editorial: Homologous serum hepatitis’, *Lancet*, 250, 6840, 8 November 1947, pp.691-2.

<sup>24</sup> H. J. Alter, P. V. Holland, P. J. Schmidt, ‘Hepatitis-associated antigen: to test or not to test?’, *Lancet*, 18 July 1970, p.142.

<sup>25</sup> Graeme Woodfield was Director of the Auckland Blood Transfusion Service from 1976 to 1998. D. G. Woodfield, interviewed by D. M. Jowitt, 12 December 2006.



Orthopaedic surgery went through blood like nothing on earth and the cardiothoracic unit drank it like it was going out of fashion.<sup>26</sup>

Wilson, who later became widely known for his work in blood coagulation and haemostatic disorders, regarded hepatitis B as a major problem for transfusion recipients.<sup>27</sup> In New Zealand, he estimated that every year ten to twelve people would be identified with posttransfusion hepatitis, and that of these, three or four would die. Patients who required large or frequent transfusions were known to be at higher risk of infection: 'In the days before cryoprecipitate and factor VIII concentrate, haemophiliacs were being treated with huge volumes of plasma just to sustain a normal life ... so it was almost guaranteed that they would get hepatitis in their lifetime'.<sup>28</sup> Nevertheless, throughout the 1960s attempts to prevent the spread of the virus were hampered by the lack of an effective screening test, and blood banks could not be sure that the blood and blood products they provided were free from contamination.

Safety is fundamental to the practice of transfusion medicine, not least because patients rely on blood bank staff to provide a trustworthy service. Interviews conducted for the purpose of this thesis reflected the importance of this issue; transfusionists and technicians who had worked for the New Zealand transfusion services repeatedly returned to the themes of patient safety and their responsibility to protect recipients from infection and other risks of transfusion.<sup>29</sup> In his classic 1970 study comparing blood donation in the UK, US, and a range of other countries, British social policy historian

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<sup>26</sup> W. Wilson, interviewed by D. M. Jowitt, 31 January 2007. Medical laboratory technologists were renamed medical laboratory scientists in the 1990s; their role included operational activities in the laboratory as well as medical research.

<sup>27</sup> Allan Anderson, a medical scientist at the Auckland Blood Transfusion Service from 1969-84, described Wilson as a leading researcher who was 'at the top of his field, not only in New Zealand; he was ranked among the top people in the world'. R. A. Anderson, interviewed by D. M. Jowitt, 8 March 2007.

<sup>28</sup> W. Wilson, interviewed by D. M. Jowitt, 31 January 2007.

<sup>29</sup> For example, concern over HIV contamination before testing began in July 1985 led Dr James Faed, Director of the Otago Transfusion Service, to recruit low risk donors to provide blood products for haemophiliac children in his region: 'My approach to HIV as a transfusionist and clinical haematologist was that I couldn't be sure of the safety of ... factor VIII and IX concentrates. I [linked] individual children to a small group of middle-aged, married, Dunedin women. The total number of donors to whom each child was exposed was minimized, to about 30 people, and the selection of donors limited to the safest available'. J. M. Faed, interviewed by D. M. Jowitt, 8 November 2006.

Richard Titmuss emphasised the dependence of the transfusion recipient on the medical profession and the system of medical care: 'he has no alternative but to trust'. Of all the hazards of transfusion, Titmuss described serum hepatitis as the 'most dangerous' and a 'major public health problem throughout the world'.<sup>30</sup>

Despite universal concerns over the safety of the supply, however, the demand for blood grew during the 1960s, and blood banks came under increasing pressure to recruit and retain donors. In New Zealand, the Auckland Regional Blood Service recorded a rapid increase in blood donations between the mid-1950s and the early 60s: 'In 1963 almost 27,000 bleedings were recorded, more than two and a half times as many as in 1954.'<sup>31</sup> In the UK the increase was equally dramatic; Titmuss found a 77 per cent rise in the annual number of donations in England and Wales between 1956 and 1967 while the total population grew by only 8 per cent.<sup>32</sup> Titmuss also investigated the expansion of blood donation in the US, where the mix of commercial and hospital-based blood bank facilities made total collection figures more difficult to obtain. Nevertheless, he estimated that the larger commercial blood banks increased their collections by 119 per cent between 1964 and 1967, and that the proportion of the blood supply obtained from paid donors increased significantly from the mid-1950s throughout the 1960s.<sup>33</sup>

To protect recipients, attempts were made to exclude potentially infectious donors. As a means of selecting 'safe' donors, blood banks used questionnaires to exclude people with a history of hepatitis, or 'yellow jaundice', from giving blood donations.<sup>34</sup> While questionnaires were undoubtedly of some benefit, they were known to be open to abuse in the US, where a high proportion of donor blood was bought and sold by commercial blood banks.<sup>35</sup> Even voluntary donors in the UK and New Zealand with no monetary incentive could provide inaccurate answers, simply because they had no knowledge of

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<sup>30</sup> R. M. Titmuss, *The Gift Relationship: From Human Blood to Social Policy*, Oxford, 1970, pp.142-3.

<sup>31</sup> L. Bryder and D. A. Dow, *Banking on Blood: Auckland Regional Blood Services 1941-1991*, p.19.

<sup>32</sup> R. M. Titmuss, *The Gift Relationship: From Human Blood to Social Policy*, p.32; p.92.

<sup>33</sup> *ibid.*, p.32; p.92.

<sup>34</sup> *ibid.*, p.144; Anon., 'Transmission of disease by blood transfusion', *British Medical Journal*, 2, 5511, 20 August 1966, p.426; W. Wilson, interviewed by D. M. Jowitt, 31 January 2007.

<sup>35</sup> R. M. Titmuss, *The Gift Relationship: From Human Blood to Social Policy*, p.144.

their past or present infectious status. As previously discussed, there is a wide spectrum of illness resulting from hepatitis B virus infections, and although some people develop the classic symptoms of hepatitis, including tiredness, nausea and jaundice, over 60 per cent will show no signs or symptoms of ill health. Furthermore, chronic carriers of the disease, whose blood is the most common source of hepatitis B virus infection, often acquire ‘silent’ disease in infancy or early childhood, and as a result can be completely unaware of their infectious status. For these reasons, donor questionnaires were of limited value in identifying infectious donors.

As an additional precaution, donated blood was screened visually to detect bilirubin, the yellow pigment responsible for jaundice in people with acute hepatitis. However, this method of detecting infectious donations was also flawed, because the level of bilirubin is not elevated in the blood of most chronic hepatitis B carriers, and therefore their blood looks no different from that of other donors. Wilson described the early screening process at the Auckland Blood Transfusion Service as very basic: ‘we had no screening procedure for our blood other than looking at the blood in the rack ... and identifying those that were yellow. We did it just by eye ... That's all that we could do’.<sup>36</sup> Like donor questionnaires, visual screening signalled an intention to protect recipients from harm, but its rudimentary nature only served to highlight the difficulties of preventing infectious blood from entering the blood supply.

Plasma and other products derived from whole blood posed an even greater risk to recipients, because they were frequently produced by pooling the blood from multiple donors. Plasma, the straw-coloured, liquid component of blood, was used widely in transfusion, but as Jennifer Stanton explained, towards the end of World War Two it was recognised that the routine practice of pooling plasma from up to 500 donors greatly increased the likelihood of contamination with serum hepatitis.<sup>37</sup> In the 1950s, the UK introduced a system of pooling the plasma of no more than ten donors to reduce this

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<sup>36</sup> W. Wilson, interviewed by D. M. Jowitt, 31 January 2007.

<sup>37</sup> J. M. Stanton, ‘Health Policy and Medical Research: Hepatitis B in the UK since the 1940s’, p.71.

risk.<sup>38</sup> Acting on the UK findings, New Zealand blood banks took this policy a step further by using ‘single donor plasma’ whenever possible, to reduce the risk of hepatitis transmission to a minimum.<sup>39</sup> Research undertaken in the UK in the mid-1960s vindicated these efforts to protect plasma recipients from viral infection: ‘When plasma from large pools is used, the incidence of [hepatitis] can reach the alarming figure of 11.9 per cent, but if the plasma pool is prepared from less than 10 [donors] the figure falls to 1.3 per cent.’<sup>40</sup>

Despite the compelling evidence for the use of small donor pools, large plasma pools collected from several hundred donors remained commonplace in the US throughout the 1950s and 1960s. In many respects, plasma suited the commercial interests within the US blood banking industry; it was cheaper to collect than whole blood, it could be drawn from donors more frequently, and it could be stored indefinitely in a freeze-dried form.<sup>41</sup> Moreover, plasmapheresis, a new method of extracting plasma introduced in the US in the mid-1960s, enabled a rapid increase in the volume of US plasma collections. In this process, blood bank staff separated the plasma for use in other patients, but returned the red cells, white cells and some plasma to the original donor. Commercial programmes used professional donors who were willing to provide their plasma for payment, sometimes several times a week.<sup>42</sup>

Titmuss argued that the focus on profit-making in commercial blood banks in the US reduced the safety of the blood supply. He pointed to a number of US studies on transfusion-related hepatitis that highlighted the dramatic difference in infection risk between voluntary donations and commercially acquired blood and blood products. In research undertaken at the prestigious US National Institutes of Health, for example, among patients who received multiple transfusions during open heart surgery, of those

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<sup>38</sup> Anon., ‘Homologous serum jaundice after transfusion of whole blood, dried small-pool plasma, dried irradiated plasma, and kaolin-treated filtered liquid plasma’, *Lancet*, 263, 6826, 26 June 1954, p.1328; R. M. Titmuss, *The Gift Relationship: From Human Blood to Social Policy*, pp.154-5.

<sup>39</sup> L. Bryder and D. A. Dow, *Banking on Blood: Auckland Regional Blood Services 1941-1991*, p.47.

<sup>40</sup> Anon., ‘Transmission of disease by blood transfusion’, p.426.

<sup>41</sup> R. M. Titmuss, *The Gift Relationship: From Human Blood to Social Policy*, p.150.

<sup>42</sup> *ibid.*, p.51.

who received primarily commercial blood, 53 per cent developed hepatitis. Among a second group who received 97 per cent of their blood from voluntary donors, there were no reported cases of posttransfusion hepatitis.<sup>43</sup> Nevertheless, despite the recognised risks of infection, during the 1960s, the demand for blood outstripped the supply, and commercial blood banks in the US found a ready market for their products.

It is clear that blood and blood products were increasingly important to the development of new surgical procedures and medical treatments in the 1960s, but that they carried a significant risk of infection. Although they could not eliminate this risk, UK and New Zealand blood banks reduced the infectious hazard through voluntary blood donation and preventive policies and procedures. In the US, the high prevalence of posttransfusion hepatitis reflected the widespread use of commercially acquired blood and the large volumes of contaminated blood entering the blood supply.<sup>44</sup>

### **The introduction of screening at the Auckland Blood Transfusion Service**

In the mid-1960s, the accidental discovery of a marker for the hepatitis B virus by Dr Baruch Blumberg, a US geneticist, led to the development of a screening test for donated blood. New Zealand transfusionists, who kept regular contact with their international colleagues, were keenly aware of overseas developments. By the late 1960s, Staveley, Director of the Auckland Blood Transfusion Service, was taking the first steps towards the introduction of hepatitis B screening in the Auckland blood bank laboratory.

In 1964, Blumberg and his research team at the US National Institutes of Health detected a novel viral antigen which they later identified as a blood marker for the presence of the hepatitis B virus.<sup>45</sup> As a newcomer to the field of hepatitis, Blumberg's findings initially met with resistance and suspicion from the established research community, but within four years he had produced convincing evidence that transfused blood containing the so-

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<sup>43</sup> *ibid.*, pp.154-8.

<sup>44</sup> H. J. Alter, email communication, 15 May 2007.

<sup>45</sup> Baruch Blumberg wrote a detailed account of the discovery of the 'Australia antigen' in his memoir, *Hepatitis B: The Hunt for a Killer Virus*, Princeton, 2002, pp.72-105.

called ‘Australia antigen’ was the cause of serum hepatitis in transfusion recipients.<sup>46</sup> To detect the antigen, Blumberg used a basic laboratory testing technique, the Ouchterlony or double diffusion method, which could be duplicated easily in most laboratories.<sup>47</sup> Towards the end of 1968, he and his team distributed kits containing Australia antigen and its antibody to medical investigators around the world, both to accelerate the collection of research data and to encourage the introduction of routine hepatitis B screening of donated blood.<sup>48</sup>

While there is no evidence that members of the TAC acquired testing kits from Blumberg’s laboratory, they were closely informed of research developments in the US. As a result of their war-time experiences and post-graduate training in the UK, TAC members maintained strong professional and personal ties with their international colleagues in the transfusion community.<sup>49</sup> In addition, their participation in the International Blood Banking System as well as attendance at overseas conferences meant that they maintained extensive networks in transfusion research. Staveley, who was involved with world-renowned New Zealand research such as the development of intrauterine transfusion, had particularly strong links with US transfusionists.<sup>50</sup> As a leading member of the committee with acknowledged expertise in transfusion medicine, he took the initiative by establishing the capacity for hepatitis B testing at the Auckland Blood Transfusion Service during the late 1960s.

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<sup>46</sup> In the 1960s, it was scientific convention to name new finds after the geographical source of the serum sample which in this case was taken from blood identified as that of an ‘Australian Aboriginal’. B. S. Blumberg, H. J. Alter, S. Visnich, ‘A “new” antigen in leukemia sera’, *JAMA*, 191, 1965, p.542; B. S. Blumberg, B. S. Gerstley, D. A. Hungerford, W. T. London, A. I. Sutnick, ‘A serum antigen (Australia antigen) in Down’s Syndrome, leukemia, and hepatitis’, *Annals of Internal Medicine*, 2, 5511, May 1967, pp.924-31; B. S. Blumberg, W. T. London, A. I. Sutnick, ‘Relation of Australia antigen to virus of hepatitis’, *Bulletin of Pathology*, 10, 1969, p.164.

<sup>47</sup> B. S. Blumberg, *Hepatitis B: The Hunt for a Killer Virus*, p.75.

<sup>48</sup> *ibid.*, p.112.

<sup>49</sup> Howie later recalled that ‘I remained in communication with [international] colleagues throughout their lives’. He also used his sabbatical leave to visit and work with transfusionists in South Africa, Australia, the US and Europe. J. B. Howie, personal communication, 20 May 2007.

<sup>50</sup> Jean Montague, Charge Sister at the Auckland Blood Transfusion Service, recalled that during the 1960s, ‘Our laboratories were working in with Professor [William] Liley [on intrauterine transfusion] and with other places. We were always getting calls from New York ... We had groups of doctors coming from all over the world ... We had people coming from all over. We had a Mrs Rothschild coming from New York, because she had the Rh[esus] problem.’ J. Montague, interviewed by D. M. Jowitt, 17 November 2006.

According to Roy Douglas, the Charge Laboratory Technologist, breaking new ground was part of the ethos of the Auckland Blood Transfusion Service. As he explained, ‘as early as 1951, the Auckland service had been ... the nation’s “Reference Centre” for matters relating to blood banking and transfusion ... we held [a] sort of leadership role’. Douglas believed that the Auckland service ‘took the responsibility seriously and tried to stay at the forefront of good practice of the time’.<sup>51</sup> US health authorities, including the National Research Council and the American Association of Blood Banks, endorsed universal hepatitis B screening of donor blood in October 1970; however, by this time Auckland had already developed a testing system. As Douglas recalled, ‘We never saw the need to wait for the NIH [National Institutes of Health], the AABB [American Association of Blood Banks], or anybody else.’<sup>52</sup>

While Staveley and his laboratory staff were undoubtedly motivated by the need to protect local transfusion recipients and to ensure that New Zealand blood banks were in the vanguard of international transfusion practice, the early introduction of screening was also influenced by other factors. From the outset, Staveley’s approach to running the service was strongly research-focused. Allan Anderson, a laboratory technologist with the Auckland Blood Transfusion Service from 1969–1984, recalled that in the 1960s ‘the service basically became a research centre. That was not actually allowable, because we were a routine laboratory doing routine tests ... But Jock developed a research arm and [attracted] guys like Roy Douglas, who was a leading light’.<sup>53</sup> In addition, Staveley had strong links with the US transfusion community. Other scientists in the blood bank laboratory, such as Wilson, were aware that Staveley’s regular contacts with US researchers such as Richard Rosenfield, who pioneered intrauterine transfusion in New York, influenced the tests that were undertaken within the Auckland service.<sup>54</sup> Lastly, the

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<sup>51</sup> R. Douglas, email communication, 25 May 2007.

<sup>52</sup> *ibid.* The TAC established a subcommittee of Charge Technologists in the late 1960s, initially to advise on technical matters around tissue typing for kidney transplantation, but subsequently on broader aspects of blood group serology. J. B. Howie, ‘History of the Transfusion Advisory Committee’, pp.3-4.

<sup>53</sup> R. A. Anderson, interviewed by D. M. Jowitt, 8 March 2007.

<sup>54</sup> W. Wilson, interviewed by D. M. Jowitt, 31 January 2007. According to his death notices, Richard Rosenfield was a long time clinician and researcher at the Mount Sinai Medical Center in New York, and a ‘distinguished authority on blood types and blood transfusion, a pioneer in exchange transfusions on “Rh babies”’, *New York Times*, 8 October 1997, online, available at:

Auckland service was under pressure to prevent hepatitis B-positive plasma from entering the Australian plasma stores. Douglas recalled that ‘colleagues at CSL ... were anxious that New Zealand plasma sent for fractionation should not contaminate their plasma [pools] ... That was a principal force to test for hepatitis’.<sup>55</sup>

Australian colleagues, some of whom had sophisticated research laboratories, were helpful in ‘proving’ the first reagents for testing.<sup>56</sup> Douglas described the process of developing testing techniques as proceeding in stops and starts, by ‘trial and time’. He had to overcome a range of technical problems: ‘we eventually found [suitable hepatitis B virus antibodies and antigens] among posttransfusion hepatitis sufferers ... the sensitivity [of the test] was low, [but] the diffusion system was better than nothing’.<sup>57</sup> Even though the Auckland Blood Transfusion Service had not acquired testing kits from Blumberg in the late 1960s, the viral laboratory at Fairfield Infectious Diseases Hospital in Melbourne had taken advantage of his offer.<sup>58</sup> By early 1970, Auckland was in communication with transfusion centres in both the US and Australia. Minutes of the March 1970 meeting of the TAC record that specimens which ‘appeared to contain [serum hepatitis] antigen and antibodies have been forwarded to ... Bethesda [the headquarters of the US Public Institutes of Health] for confirmation ... Sera were being forwarded to Melbourne also for opinions’.<sup>59</sup>

Australian transfusion services also provided assistance in mid-1970, during an outbreak of hepatitis B virus infection among patients at the Auckland Hospital Dialysis Unit.

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<http://www.nytimes.com/1997/10/08/classified/paid-notice-deaths-rosenfield-richard-e-md.html> (22 July 2009).

<sup>55</sup> R. Douglas, email communication, 25 May 2007. Once testing was established, New Zealand blood banks were also keen to ensure that plasma products prepared and stock-piled by CSL had been tested for hepatitis B. TAC minutes, 22-23 September 1971, private papers, J. B. Howie.

<sup>56</sup> In Melbourne, for example, Jakob Kaldor, a research scientist at Fairfield Infectious Diseases Hospital, had been investigating the hepatitis B antigen since the mid-1960s. C. R. Lucas, interviewed by D. M. Jowitt, 7 July 2007.

<sup>57</sup> TAC minutes, 22-23 September 1971, private papers, J. B. Howie.

<sup>58</sup> A. A. Ferris, J. Kaldor, C. R. Lucas, ‘Australia antigen and viral hepatitis: a brief review and a preliminary Australian report’, *Pathology*, 2, 1970, pp.1-8. Fairfield Hospital introduced routine testing of all viral hepatitis admissions for the Australia antigen on 1 July 1969, C. R. Lucas, ‘Hepatitis in Victoria’, paper presented at the Hepatitis B in New Zealand Workshop, 24-26 June 1982, Whakatane, private papers, C. R. Lucas.

<sup>59</sup> TAC minutes, 5-6 March 1970, private papers, J. B. Howie.



Between May 1970 and September 1971, 19 cases of hepatitis B were diagnosed.<sup>60</sup> Hepatitis testing was used to help stem the outbreak; the unit introduced weekly hepatitis B screening of staff and patients, and would not accept new patients unless they were antigen negative. Dialysis machines, which were used in the treatment of multiple patients, were a known source of cross infection. Patients already positive for the hepatitis B virus antigen were given training in home dialysis in an effort to prevent the spread of hepatitis B. Local renal specialists, who were well aware of the limitations of the early testing methods, encouraged their patients to accept very low iron counts rather than run the risk of infection through transfusion, an integral part of the therapy offered to renal patients. To increase the accuracy of screening, the Sydney Red Cross Blood Transfusion Service confirmed Auckland's results during the first four months of testing.<sup>61</sup>

During the 1960s, hepatitis B outbreaks affecting both patients and staff occurred in dialysis units worldwide.<sup>62</sup> Jennifer Stanton, who discussed the issues raised by the fatal outbreaks in UK renal dialysis units from 1965 to 1971, concluded that they 'almost certainly influenced' the timing of the implementation of hepatitis B screening tests in UK blood banks. Without the renal unit outbreaks, she contended that 'there would probably have been a longer period of exploration, of testing the tests, before implementation'.<sup>63</sup> While this was not the case in New Zealand where the impetus for testing was already established, the Auckland outbreak certainly provided a clinical focus for the further refinement of reliable testing methods.

By the late 1960s, the Auckland blood bank laboratory had acquired the equipment and expertise required for the introduction of routine screening of donated blood, the first in New Zealand. Aside from the long-awaited opportunity to reduce the risk of hepatitis B virus infection among transfusion recipients, other factors had impinged on the decision

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<sup>60</sup> E. A. Bowie, P. B. Doak, J. D. K. North, 'Hepatitis in the Auckland Dialysis Unit', *NZMJ*, 77, February 1973, pp.75-80.

<sup>61</sup> *ibid.*, p.78.

<sup>62</sup> B. P. Marmion, C. J. Burrell, R. W. Tonkin, J. Dickson, 'Dialysis-associated hepatitis in Edinburgh: 1969-1978', *Reviews of Infectious Diseases*, 4, 3, 1982, pp.619-37.

<sup>63</sup> J. M. Stanton, 'Health Policy and Medical Research: Hepatitis B in the UK since the 1940s', pp.141-2.

to develop the screening capacity, not least being the trans-Tasman agreement to supply plasma for the production of specialised blood products.

### **The challenges of hepatitis B testing during the 1970s**

The introduction of routine hepatitis B screening of all blood donations in the early 1970s had significant financial and operational implications for New Zealand blood banks. The Health Department proved reluctant to provide funding for the new screening regimen, and as tests became increasingly sophisticated and costly during the 1970s, tensions arose between the need to increase the efficiency and sensitivity of testing, and constraints on health spending.

At its September 1970 meeting, the TAC discussed the introduction of routine hepatitis B screening in New Zealand blood banks. Committee members were aware that extra staff and facilities would be needed to implement the screening process. Routine screening for syphilis, already an established practice, was inexpensive and straightforward, however, screening for a viral antigen was far more complex, and the TAC anticipated that the Health Department would be less than forthcoming with the funding required. To reduce costs and accelerate the nationwide introduction of routine screening, they proposed to standardise the testing methods and to assist one another with the materials required.<sup>64</sup> Bruce Howie, Regional Transfusion Officer for the Otago region, explained the challenges involved: ‘The Health Department was going through a great period of conservation at this time ... Not only were we looking for a suitable [screening] test ... but it was not cheap and the equipment we were using was not cheap’.<sup>65</sup>

Early in 1971, the TAC recommended that where laboratory resources were limited, screening blood donations for the hepatitis B virus should take precedence over other tests.<sup>66</sup> Recommendations that met Health Department approval were distributed in the form of official circulars to the medical superintendents of individual hospital boards.

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<sup>64</sup> TAC minutes, 10-11 September 1970, private papers, J. B. Howie.

<sup>65</sup> J. B. Howie, interviewed by D. M. Jowitt, 9 November 2006.

<sup>66</sup> TAC minutes, 25-26 February 1971, private papers, J. B. Howie.

When departmental officials had reservations about policy proposals, however, they apparently employed delaying tactics. As Howie later wrote, the TAC was ‘handicapped’ by its terms of reference as an advisory committee; it had no executive responsibilities beyond what it could achieve through ‘mutual cooperation ... and non-parochial interests, and by executive action at local levels through hospital boards’.<sup>67</sup> The distribution of the circular on hepatitis B testing was held up until September 1971, a lapse that could not be explained satisfactorily by Boyd, the departmental representative on the TAC.<sup>68</sup> In Howie’s opinion, Boyd was ‘an excellent chairman’, but departmental inaction contributed to the slower than anticipated implementation of routine hepatitis B screening.<sup>69</sup>

The delay in distributing the circular had flow-on effects. In April 1971, in response to the Auckland outbreak, Dr John Hiddlestone, Director of the Hospitals Division, sent copies of the US Centers for Disease Control (CDC) recommendations for the prevention and control of ‘haemodialysis-related hepatitis’ to hospital superintendents throughout the country.<sup>70</sup> The CDC guidelines, which focused on the importance of screening all donated blood and the monthly screening of patients and staff in dialysis units, relied on the ready availability of blood bank laboratories equipped to perform the hepatitis B test. However, as not all regions were in a position to provide this service, the value of departmental advice on the control of dialysis-related infection was markedly reduced.<sup>71</sup> Moreover, in September 1971, when the Department announced that ‘serum’ hepatitis was a notifiable disease, only the Auckland, Christchurch and Palmerston North transfusion regions could test for hepatitis B, while Wellington and Dunedin could not.<sup>72</sup>

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<sup>67</sup> J. B. Howie, ‘History of the Transfusion Advisory Committee’, p.5.

<sup>68</sup> Department of Health, Circular Letter to Hospitals, 1971/133, ‘Blood Tests’, (undated) ZABV A1073 107a, ANZA.

<sup>69</sup> J. B. Howie, interviewed by D. M. Jowitt, 9 November 2006.

<sup>70</sup> Department of Health, Circular Letter to Hospitals, 1971/54, ‘Recommendations for the Prevention and Control of Haemodialysis-Associated Hepatitis’, 16 April 1973, ZABV A1073 105c, ANZA.

<sup>71</sup> By the late 1960s, Auckland, Waikato, Wellington, Christchurch and Dunedin had established dialysis and renal transplant units. K. Figgins, personal communication, 10 January 2007.

<sup>72</sup> TAC minutes, 22-23 September 1971, private papers, J. B. Howie.

In regions where screening was in place, early results were encouraging. There was a notable reduction in morbidity and mortality from posttransfusion hepatitis:

In Christchurch, during the year preceding [hepatitis B] testing, there were five reports of post-transfusion hepatitis ... Since testing began, there has been only one report of post-transfusion hepatitis ... In Auckland, virtually all severe hepatitis sufferers are admitted to the Infectious Diseases Unit ... in 1969, 74 patients were admitted; 1970, 54; in 1971, 27 ... During the fifteen months prior [to hepatitis B testing] there were 7 sufferers from post-transfusion hepatitis, 2 of whom died ... testing began in Auckland in March 1971 and in the twelve months subsequent to June 1971, there were no cases of post-transfusion hepatitis.<sup>73</sup>

By early 1973, the TAC could describe the hepatitis B screening programme as 'satisfactory', but cautioned that 'the situation should be kept under review'.<sup>74</sup> Initially, screening presented an operational challenge for blood banks. The 'first-generation' hepatitis B tests usually produced results within 24-48 hours but could take up to five days to produce a positive result. Howie explained the difficulty this posed for blood banks: 'if you have bled 500 donors you want an answer the same day ... not only are you delaying all that fresh blood but you are unable to produce all the products you want from it ... the sooner you work with it, the better the yield'.<sup>75</sup> Counter-electrophoresis, a new method of testing introduced in 1972, greatly increased the speed of hepatitis B screening. Results could be seen within an hour which suited the schedule of blood banks which aimed to process a unit of blood within 12 hours; however, in spite of the improved sensitivity of this test, counter-electrophoresis still only detected carriers with high serum concentrations of the hepatitis B antigen.<sup>76</sup>

In the early 1970s, the introduction of hepatitis B testing in blood banks worldwide motivated commercial enterprises to start producing readymade testing kits. The profit-

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<sup>73</sup> P. B. Booth, J. M. Staveley, 'Hepatitis-associated antigen testing by the New Zealand Blood Transfusion Services', *Supplement to the Bulletin of the Post-Graduate Committee in Medicine, University of Sydney*, July 1973, p.64.

<sup>74</sup> TAC minutes, 1-2 March 1973, private papers J. B. Howie.

<sup>75</sup> J. B. Howie, interviewed by Deborah Jowitt, 9 November 2006.

<sup>76</sup> TAC minutes, 23-24 May 1977, private papers, J. B. Howie.

making potential from the sale of these kits was immense since blood bank policies invariably required every donation to be screened. Commercial kits were more sensitive and convenient to use; however, they involved a significant financial outlay.<sup>77</sup> The Burroughs-Wellcome ‘hepatest’, for example, which was introduced into New Zealand in 1975, was an improvement on counterelectrophoresis, but much more expensive.<sup>78</sup> To use the hepatest, the Auckland Blood Transfusion Service, which was collecting about 75,000 blood donations annually during the early 1970s, was confronted by an enormous increase in costs. To overcome this problem, Anderson and Wilson, now senior scientists in the Auckland Blood Service laboratory, used a novel system they called ‘micro-modification’ to ration the testing materials in the Burroughs-Wellcome kits.<sup>79</sup> While the company frowned on this practice, it could do little about it. For their part, the two scientists had no compunction about making the most use of the costly kits. As Wilson explained, ‘It was all about money. It was terribly expensive [to use the commercial test kits]. It always came down to money and the overseas commercial firms charging enormous amounts of money.’<sup>80</sup>

Financial pressure was exerted both by the commercial companies and by the Health Department. Departmental officials, ever mindful of economising on costs, continually reminded blood bank staff of the need to minimise spending on screening. In the mid-1970s, when the American-based company Abbott Laboratories began producing the ‘Abbott-kit’, the competing companies took an aggressive approach to promoting their own products, targeting smaller hospitals that were less likely to be influenced by the main centres. Abbott marketed their radioimmunoassay test as more sensitive than the ‘hepa-test’ but there was a significant price differential; the ‘hepa-test’ cost 30 cents per test while the ‘Abbott-kit’ cost 80 cents.<sup>81</sup> In August 1975, Dr R. Dickie, Director of the Hospitals Division, complained to medical superintendents and regional transfusion

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<sup>77</sup> R. Douglas, email communication, 19 July 2007.

<sup>78</sup> The ‘hepatest’, which used a reverse passive haemagglutination technique, was widely used in New Zealand in the 1970s.

<sup>79</sup> R. A. Anderson, interviewed by D. M. Jowitt, 8 March 2007; R. A. Anderson, ‘A new haemagglutination test for hepatitis B antibody’, *New Zealand Journal of Medical Laboratory Technology*, July 1979, pp.52-3.

<sup>80</sup> W. Wilson, interviewed by D. M. Jowitt, 31 January 2007.

<sup>81</sup> R. Douglas, email communication, 20 May 2007.

officers that there was ‘an excessive amount of promotional and propaganda activity in New Zealand by commercial companies advocating their own particular brand of testing’. Dickie, who was focused on cost containment, appeared to have little appreciation of the broader issues involved in blood bank operations. His stated concerns, that some hospital boards might adopt ‘very expensive ... techniques when ... this is neither necessary nor desirable for voluntary blood donors’, reflected his narrow view of hepatitis B screening.<sup>82</sup>

In the late 70s, the use of radioimmunoassay testing became standard practice in New Zealand. To reduce expenses, Anderson started reusing the components of the ‘Abbott-kit’ in the Auckland blood transfusion laboratory.<sup>83</sup> He recalled that ‘Instead of ... \$1.50 per test, we were getting the cost down to less than 10 cents which made good sense economically because we couldn’t afford it [otherwise]’.<sup>84</sup> Not all centres took this approach; Auckland, which had the largest donor register, had the greatest incentive to reduce the costs of screening. Graeme Woodfield, who succeeded Staveley as Director of the Auckland Blood Transfusion Service on his retirement in 1976, found himself constantly balancing the competing pressures of economy and quality of service. TAC minutes from mid-1977 record the urgent need for a ‘more sensitive test which is economically feasible ... especially in the northern regions of the country’.<sup>85</sup> From Woodfield’s perspective, it was a matter of maintaining a high standard of screening in an era of cost-cutting without making too many waves: ‘We were trying to save the health service money ... we could see that the modified test that we’d produced was highly sensitive and specific ... but it wasn’t liked by the commercial firms. They disliked it immensely for obvious reasons’.<sup>86</sup>

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<sup>82</sup> Department of Health, Circular Letter No. Hosp. 1975/150, 8 August 1975, ‘H. B. Ag testing of blood donors’, ZABV A1073 96a, ANZA.

<sup>83</sup> R. A. Anderson, ‘An inexpensive radioimmunoassay for hepatitis B antigen detection’, *New Zealand Journal of Medical Laboratory Technology*, April 1982, pp.30-1.

<sup>84</sup> R. A. Anderson, interviewed by D. M. Jowitt, 8 March 2007.

<sup>85</sup> TAC minutes, 23-24 May 1977, private papers, J. B. Howie.

<sup>86</sup> D. G. Woodfield, interviewed by D. M. Jowitt, 12 December 2006.

The friction between blood bank laboratories and commercial firms came to a head at a hepatitis conference sponsored by Abbott Laboratories in Whakatane in 1982. When it was Anderson's turn to present, he described 'the details of how we were doctoring all the commercial tests ... [and] the American guy from Abbott said, you know Allan, back in the States you'd be in prison now because that's against the law. I said, I know that but it isn't against the law here – yet!'<sup>87</sup> Abbott Laboratories was eager to bind New Zealand to a nationwide contract for radioimmunoassay reagents and equipment, but blood bank staff members were equally keen to avoid such an arrangement. Roy Douglas, Chief Laboratory Technologist at the Auckland Blood Transfusion Service, explained that 'Any glitch in supply of reagents or malfunction of equipment would [have] jeopardise[d] the blood supply and we were not prepared to tolerate that risk ... given the importance of testing for hepatitis'.<sup>88</sup>

From the early 1970s, New Zealand blood banks faced a challenge to finance and implement hepatitis B screening. When commercial test kits came on the market, costs rose dramatically, but so did the speed of processing and the sensitivity of testing. While the Health Department was reluctant to fund even the most basic tests, blood banks were under pressure to adopt the most efficient and sensitive screening methods available. During the 1970s, scientists at the Auckland Blood Transfusion Service developed innovative techniques in response to the rising costs of testing, the limited funding available, and the need to maintain an internationally accepted standard of screening.

### **Other outcomes of the hepatitis B screening policy**

While the introduction of routine hepatitis B screening in blood banks led to a marked reduction in the prevalence of posttransfusion hepatitis in New Zealand, there were other, less immediate outcomes of the policy. Screening produced the first epidemiological data on the prevalence of hepatitis B virus infection in New Zealand, and revealed those donors whose blood had high levels of hepatitis B antibody which could be used to protect people exposed to the virus.

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<sup>87</sup> R. A. Anderson, interviewed by D. M. Jowitt, 8 March 2007.

<sup>88</sup> R. Douglas, email communication, 20 May 2007.

New Zealand blood banks routinely collected statistical information on blood donation and transfusion. In many respects, statistics on New Zealand blood donors conformed to those of other western countries such as the UK and Australia. However, by 1973 local data indicated a much higher prevalence of hepatitis B carriage among Maori and Pacific peoples than among European New Zealanders.<sup>89</sup> These data were supported by studies undertaken throughout the Pacific during the mid-1970s that found pockets of high hepatitis B prevalence among people on many island groups.<sup>90</sup>

Statistics compiled by the five transfusion centres throughout New Zealand also showed a marked North-South differential in infection rates. Hepatitis B prevalence was highest in Auckland (0.32 per cent), and lowest in Christchurch (0.13 per cent). This was related to the higher Polynesian population in Auckland, where 5.3 per cent of 1244 Maori and Pacific donors tested positive for hepatitis B carriage. Furthermore, data collected by the Waikato Hospital blood bank laboratory suggested a marked ethnic differential in the prevalence of chronic hepatitis B virus infection in the Waikato region, where there was a substantial Maori population. While only 0.3 per cent of Waikato blood donors were positive for chronic hepatitis B, a survey of 300 inmates at Waikeria Borstal, a penal institution for young men, found that over 35 per cent of the 153 Maori inmates tested were hepatitis B carriers compared with only one of the 150 European inmates.<sup>91</sup>

In 1977, the TAC reviewed the prevalence of hepatitis B positive donors on the basis of more sensitive screening methods. The percentage of new donors found to be hepatitis B carriers ranged from 2.4 per cent in Auckland to 0.17 per cent in Otago. In spite of the low overall prevalence of hepatitis B virus infection throughout the country, distinct ethnic and geographic differences were evident. In Auckland, data on new donors

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<sup>89</sup> See, for example, Y. Cossart, 'Epidemiology of serum hepatitis', *British Medical Bulletin*, 28, 21, 1972, pp.156-61; C. R. Lucas, 'Hepatitis in Victoria'; P. B. Booth, J. M. Staveley, 'Hepatitis-associated antigen testing by the New Zealand Blood Transfusion Services', p.64.

<sup>90</sup> See, for example, F. J. Austin, T. Maguire, J. A. R. Miles, 'The occurrence of hepatitis B antigen and antibody in some population groups in the southwest Pacific region', *American Journal of Tropical Medicine and Hygiene*, 23, 3, 1974, pp.489-94; B. S. Blumberg, S. Mazzur, K. Herzog, 'Australia antigen in the Solomon Islands', *Human Biology*, 46, 1974, pp.239-62.

<sup>91</sup> C. M. Boveington, 'The incidence of hepatitis associated antigen in the Waikato', *New Zealand Journal of Medical Laboratory Technology*, July 1973, pp.59-61.



reflected ‘a phenomenon of two populations with different incidences [sic] of [hepatitis B antigen] positive tests. The Caucasian population with a very low incidence [sic] and a Polynesian population with a high incidence [sic] of ... 6-8%’.<sup>92</sup> These results were supported by a survey conducted among Samoan immigrants in Christchurch by Dr Peter Booth, Regional Transfusion Officer for Canterbury, and Dr Joan Faoagali, a microbiologist at the Christchurch Hospital laboratory. The prevalence of hepatitis B carriage among Christchurch donors was less than 0.2 per cent; however, of the 96 Samoans surveyed, four per cent were hepatitis B carriers, while 54 per cent had hepatitis B antibodies, indicating past infection with the virus.<sup>93</sup>

The medical profession was unaware of the significance of the ethnic differential in prevalence rates until the early 1980s, when an association between hepatitis B carriage and liver cancer was confirmed.<sup>94</sup> In the 1970s, blood bank data were thought to have no particular implications for the health of Maori and Pacific carriers. Medical researchers considered ‘genetic susceptibility’ to be a possible cause for the uneven distribution of the virus worldwide, and were only beginning to gain an understanding of the long term consequences of chronic hepatitis B carriage.<sup>95</sup> Interpretations of statistical data were conditioned by established medical assumptions around ethnicity and infectious disease. Christine Boveington, a Waikato Hospital blood bank scientist, for example, theorised that, like the tuberculosis bacilli, the hepatitis B virus might present a particular challenge to indigenous people: ‘possibly the Maori has had insufficient opportunity in terms of time, to develop [an] adequate immune response’.<sup>96</sup>

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<sup>92</sup> TAC minutes, 23-24 March 1977, private papers, J. B. Howie.

<sup>93</sup> J. L. Faoagali, P. B. Booth, ‘Hepatitis B surface antigen and antibody among Samoans living in Christchurch’, NZMJ, 85, 13 April 1977, pp.278-80.

<sup>94</sup> R. P. Beasley, L. Y. Hwang, C. Lin, C. Chien, ‘Hepatocellular carcinoma and hepatitis B virus: a prospective study of 22,707 men in Taiwan’, 318, 8256, *Lancet*, 21 November 1981, pp.1129-33; WHO, *Prevention of Liver Cancer: Technical Report Series 691*, Geneva, 1983.

<sup>95</sup> J. L. Faoagali, D. Gidall, ‘Hepatitis B surface antigen in notified cases of viral hepatitis’, NZMJ, 84, 28 July 1976, p.52; W. Szmunes, ‘Recent advances in the study of the epidemiology of hepatitis B’, *American Journal of Pathology*, 81, 3, December 1975, pp.629-49; WHO, *Advances in Viral Hepatitis: Report of the WHO Expert Committee on Viral Hepatitis: Technical Report Series 602*, Geneva, 1977.

<sup>96</sup> C. M. Boveington, ‘The incidence of hepatitis associated antigen in the Waikato’, pp.59-61.

There was at least one further outcome of the screening test. In the mid-1970s, medical researchers realised that donors with antibodies to the hepatitis B virus were a useful source of hepatitis B immunoglobulin. Immunoglobulins fight infections by binding to specific bacterial or viral antigens, and hepatitis B specific immunoglobulin could be used as a form of ‘passive’ immunisation for people exposed to the virus.<sup>97</sup> The screening test identified donors with high serum concentrations of immunoglobulin whose plasma could be sent to Melbourne for processing. Until a vaccine became available early in the 1980s, hepatitis B immunoglobulin was the only treatment for at risk patients, health care workers, and other at risk groups exposed to the virus.

Early in 1975, to provide protection for hospital and laboratory staff considered to be at high risk of hepatitis B virus infection, the TAC recommended that ‘all regions make efforts to identify donors of Hepatitis B antibody so that production of the immunoglobulin may commence’.<sup>98</sup> In 1977, Booth and Faoagali identified Samoan New Zealanders with high antibody titres as an ‘important and valuable source of this substance ... if larger quantities are required’.<sup>99</sup> In the meantime, CSL in Melbourne provided New Zealand blood banks with immunoglobulin from donors in Papua New Guinea. Unlike Australia, Papua New Guinea had a high prevalence of hepatitis B virus infection and was consequently an excellent source of the immunoglobulin.<sup>100</sup> By early 1979, supplies of hepatitis B immunoglobulin had increased to the point that the TAC could recommend passive immunisation for babies born to mothers who had been infected in pregnancy, and for people whose work entailed frequent exposure to the hepatitis B virus such as the staff of renal dialysis units.<sup>101</sup>

Blood bank statistics, which derived solely from donor groups, did not necessarily represent the wider population. They did, however, provide the first indication of the

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<sup>97</sup> Passive immunity to viral and bacterial antigens can be induced by injecting serum containing antibodies. Ministry of Health, *Immunisation Handbook 2006*, p.42.

<sup>98</sup> TAC minutes, 6-7 March 1975, private papers, J. B. Howie.

<sup>99</sup> J. L. Faoagali, P. B. Booth, ‘Hepatitis B surface antigen and antibody among Samoans living in Christchurch’, pp.278-80.

<sup>100</sup> TAC minutes, 25-26 September 1975, private papers, J. B. Howie.

<sup>101</sup> TAC minutes, 13-14 September 1979, private papers J. B. Howie.

relatively high prevalence of hepatitis B virus infection in Maori and Pacific communities, and of a marked ethnic differential in infection rates. In the 1970s, hepatitis B immunoglobulin was the only preventive measure against hepatitis B virus infection, and as such, was a valuable by-product of the screening process.

## **Conclusion**

The appointment of the TAC in 1963 initiated a period of significant development within the New Zealand transfusion services. TAC members, some of whom had lobbied for changes to the fragmented system of transfusion for over a decade, rapidly enacted measures to improve patient safety and develop the capacity of the regional services to meet the growing need for blood and blood products. In addition, they proved highly influential in the development and implementation of transfusion policy, using their advisory role at a national level and their clinical presence within their individual hospital boards to advance their policy agenda.

During the 1960s, New Zealand blood banks, like those in other western countries, used the limited means at their disposal to reduce the risk of serum hepatitis among transfusion recipients. When a test to detect the hepatitis B virus was developed in the US in the late 1960s, TAC members were quick to recognise the need to develop the testing capability of New Zealand blood banks. The committee was keenly aware of the need to maintain a high standard of transfusion practice in New Zealand, an issue of increasing importance as a result of the agreement with Melbourne-based CSL to provide local plasma in return for fractionated blood products.

Staveley, who took a leading role in the TAC on account of his expertise in transfusion medicine, his involvement in ‘cutting edge’ research, and his position as director of the country’s largest transfusion service, initiated hepatitis B testing in New Zealand. By the late 1960s, he had developed a strong research capability within the Auckland transfusion services in response to the rapidly growing demand for specialist knowledge and technical expertise in transfusion. As a consequence, Auckland was well-equipped to

develop the capacity for hepatitis B screening, and was the first to trial the use of hepatitis B screening as a control measure during a clinical outbreak.

Members of the TAC were highly motivated to introduce hepatitis B screening, not only to reduce the risks of posttransfusion hepatitis but also to secure continued participation in the trans-Tasman plasma exchange. Health Department officials, on the other hand, demonstrated an ongoing ambivalence towards the process, which reflected both their limited understanding of the operational aspects of transfusion, and their strong focus on cost containment. During the 1970s, there were continual tensions between the need to improve the efficiency and ease of screening and the economising tendencies of the Department. Scientists in the Auckland transfusion service became particularly adept at modifying test kits to achieve the required standard of screening within capped funding allocations.

Routine screening of donated blood led to an immediate reduction in cases of posttransfusion hepatitis. However, there were other outcomes of the introduction of the screening test; transfusion services identified hepatitis B antibody positive donors who were a potential source of protective immunoglobulin, and produced the first epidemiological data on the prevalence of hepatitis B virus infection in New Zealand. These data provided the earliest indication that the situation in New Zealand might differ from that of other Western countries, an issue which would come to prominence in the mid-1980s.

## **CHAPTER THREE**

### **AN OCCUPATIONAL HAZARD:**

### **HEPATITIS B AND HEALTH CARE WORKERS**

#### **1970–1980**

In late 1970, the Medical Superintendent-in-Chief of Wellington Hospital approached the Health Department to investigate the death of a trainee laboratory technician from fulminant hepatitis infection.<sup>1</sup> Departmental officials were aware of the fatalities among health care workers during the hepatitis B outbreaks in UK dialysis units in the late 1960s, but the sudden demise of the young Wellington woman brought home the occupational hazards of the disease. The subsequent inquiry had a direct impact on policy responses; the Health Department urged hospital boards to establish infection control committees as a means of preventing the spread of hepatitis in hospitals, while laboratory practices and procedures came under close scrutiny and policy guidance.<sup>2</sup>

New Zealand initiatives reflected a broader preoccupation with health care workers as an 'at risk' group. In the UK, as a result of the outbreaks in dialysis units in the late 1960s, health care workers were already at the forefront of the policy agenda. In the US, where hepatitis B screening was used widely in blood banks and hospitals, the high prevalence of infection among health care workers was a cause for concern. Nevertheless, proposals to introduce the routine screening of health care workers met with a mixed reaction; in the UK, where screening had proved useful as an infection control measure, there was support for its limited use, whereas in the US, screening was widely regarded as an unwarranted intrusion on workers' rights. In New Zealand, the Epidemiology Advisory

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<sup>1</sup> Hiddlestone to EAC, 'Laboratory acquired infection of serum hepatitis', 13 January 1972, AAFB 632 WZ788 151 29/19, ANZW.

<sup>2</sup> F. B. Desmond, 'Report into the Death of the Late Janet Hicks', September 1971, AAFB 632 WZ788 151 29/19, ANZW.

Committee (EAC) was quick to reject the notion of routine screening, which set a precedent for local policy makers throughout the 1970s.

The increasing focus on health care workers and on hospitals as sites of infection during the 1970s did not mean that other, much larger at risk groups were ignored by the medical and scientific community. Once a hepatitis B test became widely available, research into the virus and its effects expanded rapidly. Researchers found that hepatitis B was endemic in Sub-Saharan Africa, South-East Asia, China, and the Pacific, and that in these areas most infections occurred in infancy and early childhood. In contrast, hepatitis B was uncommon in Western countries except among adults exposed to the virus through their occupations, their sexual activities, medical care for chronic illness, or illicit drug use. In New Zealand, doctors presumed a similar ‘first world’ pattern existed, and local prevalence studies reflected this assumption.

This chapter will begin by considering the hazardous nature of laboratory work in the 1960s, and the growing awareness of the risks to which workers were regularly exposed. The impact of the death of a local laboratory worker in 1970 will then be discussed, as will the conflicting views on the proposal to introduce routine hepatitis B screening of health care workers. The consensus that emerged from the international debates on screening and the management of infected health care workers in the early 1970s will be considered, as well as the struggles over worker compensation in the mid-1970s. Finally, prevalence studies will be discussed, with reference to the development of hepatitis B policy in New Zealand during the 1970s.

### **Serum hepatitis: an occupational hazard for laboratory workers in the 1960s**

In the 1960s, despite growing awareness of the occupational hazards of ‘serum’ hepatitis, few safeguards were in place to protect health care workers from exposure to the hepatitis B virus.<sup>3</sup> During their routine duties in blood banks and hospitals, laboratory workers, in

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<sup>3</sup> Until 1978, when the official nomenclature for ‘serum’ hepatitis was changed to ‘hepatitis B’ in New Zealand, the two terms were used interchangeably. Anon., ‘News: Infectious diseases changes’, NZMJ, 10 May 1978, p.328.

particular, had frequent contact with blood and blood products, yet they paid little regard to the risks of hepatitis B virus infection.

From the early 1950s, when the first reports of serum hepatitis among health care workers began to emerge, laboratory workers were singled out as an occupational group at particular risk of acquiring the disease.<sup>4</sup> The 1953 report of the World Health Organization (WHO) Expert Committee on Viral Hepatitis, for example, acknowledged that there were ‘certain occupational procedures such as the processing of blood in blood banks and examination of blood in hospital laboratories during which infection with this virus can occur’.<sup>5</sup> The second report, published in 1964, had a broader professional focus, but still emphasised laboratory workers as a high risk group.<sup>6</sup> Recognition of the hazards of routine laboratory work by international experts did not, however, translate into safer workplace practices. Throughout this period, the techniques and equipment in general use in blood banks and hospital laboratories put workers at continual risk of exposure to the hepatitis B virus.

In New Zealand, viral hepatitis first appeared on the agenda of the Health Department Epidemiology Advisory Committee (EAC) in early 1967.<sup>7</sup> At its meeting in March 1967, the EAC adopted the 1964 report of the WHO Expert Committee on Viral Hepatitis as a guide to decision-making on this issue. From an occupational perspective, however, the WHO report offered little advice on the control of serum hepatitis over and above the measures recommended to prevent cross-infection between patients.<sup>8</sup> With no test to

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<sup>4</sup> S. Leibowitz, L. Greenwald, I. Cohen, J. Litwins, ‘Serum hepatitis in a blood bank worker’, *JAMA*, 140, 17, 27 August 1949, pp.1331-3; C. Kuh, W. E. Ward, ‘Occupational virus hepatitis: An apparent hazard for medical personnel’, *JAMA*, 143, 17 June 1950, pp.631-5; M. L. Trumbell, D. J. Greiner, ‘Homologous serum hepatitis: an occupational hazard to medical personnel’, *JAMA*, 145, 31 March 1951, pp.965-7.

<sup>5</sup> WHO, *Expert Committee on Hepatitis: First Report: Technical Report Series No. 62*, Geneva, 1953, p.14.

<sup>6</sup> WHO, *Expert Committee on Hepatitis: Second Report: Technical Report Series No. 285*, Geneva, 1964, p.10.

<sup>7</sup> The EAC was formed in October 1959 to advise the government and the Health Department on the control of communicable diseases and other ‘epidemiological matters’. EAC minutes, 12 October 1959, AAFB 786 8, W3045/8, ANZW; *AJHR*, 1961, H-31, p.87.

<sup>8</sup> These recommendations focused on the use of sterile disposable equipment and proper cleaning and sterilisation of reusable equipment. In the 1950s and 60s, mass produced, single-use syringes were introduced in place of reusable glass and metal, while disposable gloves and syringes became central to

detect the presence of the hepatitis B virus, health officials worldwide appeared to have an almost fatalistic approach to the risks of occupational exposure. A report published by the UK Public Health Laboratory Service in 1968, for example, concluded that ‘our ignorance of the hepatitis viruses makes any scheme of preventative measures to some extent speculative’.<sup>9</sup>

In the mid-1960s, as Chapter Two discussed, hepatitis B was primarily seen as a problem affecting transfusion recipients, and there was no apparent pressure to develop policies to reduce occupational risk. The mouth pipette, for instance, which was widely used in laboratories, had the potential to expose workers to direct contact with blood specimens.<sup>10</sup> Kathy Figgins, a laboratory scientist at the Auckland Blood Transfusion Service from 1968 to 1972, used mouth pipettes regularly during the 1960s.<sup>11</sup> The risks of exposure were theoretically reduced by the length of the pipette, but it was her experience that ‘when people were chatting and turning their heads to talk, you didn’t notice blood going up the tube into your mouth’.<sup>12</sup> The technique was particularly hazardous in blood bank laboratories, where laboratory workers continually handled blood and blood products. Walter Wilson, a laboratory scientist at the Auckland service from 1965, recalled that mouth pipettes were used until the mid-1970s, and that ‘everybody who worked in the lab for more than twelve years had either had [sub-clinical] hepatitis or an identified episode of hepatitis.’<sup>13</sup>

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infection control strategies. WHO, *Expert Committee on Hepatitis: Second Report: Technical Report Series No. 285*, p.22.

<sup>9</sup> This report was cited by Dr F. B. Desmond, the Wellington pathologist responsible for the ‘Report into the Death of the Late Janet Hicks’, AAFB 632 WZ788 151 29/19, p.11.

<sup>10</sup> The ubiquitous nature of the mouth pipette was illustrated by the 1973 WHO report on viral hepatitis, in which the ‘Laboratory Code of Practice’ included the instruction that ‘the mouth should never be used for pipetting’. WHO, *Report of the WHO Scientific Group on Viral Hepatitis: Technical Report Series No. 512*, Geneva, 1973, p.48.

<sup>11</sup> Figgins used a Pasteur pipette while at the blood service, where she was involved in early hepatitis B testing. These pipettes have a rubber bulb at the end of a tapered glass tube, and are hand rather than mouth operated. However, she used mouth pipettes regularly in her previous position in a pathology laboratory in Hamilton. K. Figgins, personal communication, 10 January 2008.

<sup>12</sup> The mouth pipette was approximately 30 centimetres long.

<sup>13</sup> W. Wilson, interviewed by D. M. Jowitt, 31 January 2007.



In retrospect, attitudes towards occupational health and safety in the 1960s appear exceedingly relaxed. Drinking, eating and smoking were all tolerated at the laboratory benches. As Wilson explained, ‘We didn’t think anything about it ... when I first worked in the lab we were doing cholesterols, which used ether. Somebody had done the cholesterols and tipped all the stuff down the sink, then someone else put their cigarette butt [in] and the ether exploded!’<sup>14</sup> This cavalier approach to laboratory safety was apparently universal; Dr Cyril Levene, a New Zealand immunologist who worked on the ‘Australia antigen’ in Baruch Blumberg’s laboratory in Philadelphia from 1965 to 1967, recalled that even the prestigious laboratories of the US National Institutes of Health had a *laissez-faire* attitude in this regard.<sup>15</sup> Levene later wrote that ‘We did not have any problems in drinking and eating and smoking in the lab ... Many a test had to be repeated when ash got into the [specimen] tubes, and who knows what went into my mouth’.<sup>16</sup>

Safety precautions, when they were implemented, appeared to be a response to individual incidents rather than part of a broader impetus to reduce occupational risk. Tighter safety regulations were finally imposed in Blumberg’s laboratory, but only after several laboratory staff developed hepatitis B. Levene, who had a sub-clinical infection, described the change in practice in 1967 once a connection was made between the casual handling of laboratory specimens and the development of the disease:

Around the same time [that I developed antibodies to the hepatitis B virus] ... there were some cases in the staff of people who became jaundiced and were ‘infected’ with Hepatitis B antigen ... Before that time, we had not taken any special precautions in handling specimens ... as the association between the [Australia antigen] and Hepatitis had not been proved. Of course once it was realised, there were strict precautions taken, and all [laboratory workers] wore protective gloves ...<sup>17</sup>

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<sup>14</sup> *ibid.*

<sup>15</sup> As the previous chapter discussed, the ‘Australia’ antigen was the name used for the hepatitis B antigen when it was first identified in Blumberg’s laboratory in 1964.

<sup>16</sup> C. Levene, email communication, 24 January 2007.

<sup>17</sup> *ibid.*

Attitudes towards the occupational hazards of hepatitis B began to change more widely in the late 1960s as a result of major outbreaks of the disease that occurred among patients and staff in UK renal dialysis units. These outbreaks, which attracted worldwide attention, caused significant fatalities. During the most severe outbreak, which occurred in the Renal Unit of the Royal Infirmary of Edinburgh between mid-1969 and mid-1970, there were 40 cases of serum hepatitis, of which seven patients, two laboratory technicians and two transplant surgeons died.<sup>18</sup>

Interviews conducted nearly four decades later suggest that the events in Edinburgh made an impression on laboratory workers as far away as New Zealand. Wilson recalled that ‘the Edinburgh epidemic sent shock waves throughout the entire world ... It ... was the trigger for [wider recognition of] the serious nature of hepatitis B ... [that it spread not just through transfusion but] the virus could transmit by blood splatter, drops, cuts ...’<sup>19</sup> Dr Graeme Woodfield, Director of the Auckland Blood Transfusion Service from 1976 to 1998, who completed a PhD in pathology in Edinburgh in the late 1960s, was personally affected by the outbreak. A young technician in his laboratory who had been involved in early hepatitis B work ‘got infected and died of a hepatitis infection ... I have taken a particular interest in that disorder ever since’.<sup>20</sup>

While the renal unit outbreaks had no immediate impact on work practices in New Zealand laboratories, in the UK, as Jennifer Stanton explained, they ‘changed matters drastically’.<sup>21</sup> Blood, which had previously ‘enjoyed a favourable image’, gained a deadly reputation: ‘Not only would samples from patients with the disease be handled as potentially lethal substances, but all blood samples acquired a new aura of risk.’<sup>22</sup> The outbreaks also influenced medical perceptions of the disease; Stanton concluded that they ‘had a major impact on the way that the medical profession and policy makers

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<sup>18</sup> B. P. Marmion, C. J. Burrell, R. W. Tonkin, J. Dickson, ‘Dialysis-associated hepatitis in Edinburgh: 1969-1978’, pp.619-37.

<sup>19</sup> W. Wilson, interviewed by D. M. Jowitt, 31 January 2007.

<sup>20</sup> D. G. Woodfield, interviewed by D. M. Jowitt, 12 December 2006.

<sup>21</sup> J. M. Stanton, ‘Health Policy and Medical Research: Hepatitis B in the UK since the 1940s’, p.208.

<sup>22</sup> *ibid.*, p.207; p.138.

constructed hepatitis B. [It was] Now seen primarily as an occupational hazard of health care workers ...[and] as a far more threatening hazard than before'.<sup>23</sup>

In New Zealand, these perceptual changes occurred more slowly, perhaps because there was limited first-hand experience of cross infection in local dialysis units and no associated staff fatalities. Furthermore, as Chapter Two discussed, by 1970, when the Auckland dialysis outbreak started the hepatitis B test was already available, albeit in a rudimentary form, to guide preventive measures and control cross infection.<sup>24</sup> While there is evidence that pathologists of the Auckland Hospital Board discussed the introduction of measures to minimise the risk of hepatitis B in laboratories, there was no widespread change to the most hazardous work practices such as the use of mouth pipettes.<sup>25</sup> Moreover, an inquiry initiated by the Health Department in late 1970 into laboratory procedures at Wellington and Hutt hospitals found that improvements in techniques, training and working environments were urgently needed to protect laboratory workers from infection.<sup>26</sup>

In the 1960s, then, as the result of the increased demands on blood banks and hospital laboratories, the retention of risky techniques and equipment, and the casual attitudes towards occupational health and safety, New Zealand laboratory workers were at high risk of exposure to hepatitis B. The Health Department took no steps to reduce risk or prevent infection; however, international experience suggested that until severe or fatal cases of infection occurred, health authorities were unlikely to impose safety precautions, or to challenge established work practices.

### **The outcomes of an investigation into the death of a local laboratory worker**

New Zealand health officials, like their counterparts in the UK and US, responded more promptly to significant events, than to gradual pressures for change. While moves were

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<sup>23</sup> *ibid.*, p.141.

<sup>24</sup> E. A. Bowie, P. B. Doak, J. D. K. North, 'Hepatitis in the Auckland Dialysis Unit', pp.75-80.

<sup>25</sup> Becroft to Hiddlestone, 'Laboratory hygiene', 16 November 1971, AAFB 632 WZ788 151 29/19, ANZW.

<sup>26</sup> F. B. Desmond, 'Report into the Death of the Late Janet Hicks', AAFB 632 WZ788 151 29/19.

afoot to promote safer working conditions in hospital laboratories, the unexpected death of a young laboratory worker was the stimulus for the Health Department to act on the introduction of workplace policies to protect health care workers from exposure to hepatitis B.

In December 1970, a 20 year old trainee technologist at the Hutt Hospital laboratory died suddenly from a fulminant hepatitis infection. The Medical Superintendent-in-Chief of Wellington Hospital immediately approached the Health Department to undertake an independent inquiry into this 'tragic fatality'.<sup>27</sup> The Department responded rapidly; within a week, Dr John Hiddlestone, Director of the Hospitals Division, had asked Wellington pathologist Dr F. B. Desmond, Honorary Secretary of the New Zealand Society of Pathologists, to investigate the circumstances surrounding Janet Hicks' illness and untimely death.<sup>28</sup>

Desmond presented his report to Hiddlestone nine months later, in September 1971. After some consideration, he had concluded that the young trainee had been exposed to serum hepatitis during her work in the pathology laboratories at Wellington Hospital where she had regularly handled specimens from the dialysis, kidney transplantation, and cardiac surgery units. Attempts to detect the hepatitis B antigen had been unsuccessful due to the rudimentary nature of the testing in the Wellington Hospital laboratory, but it was the context in which her case occurred, rather than the laboratory results, that had convinced Desmond of the cause of Hicks' death. From his review of the 'voluminous recent literature on the subject of hepatitis', he declared that 'There is now no doubt that workers in pathology laboratories in general and chemical laboratories sections in particular are at greater risk of contracting hepatitis [B] than the population at large.' He attributed the increased occupational risk to the rise in 'modern' medical therapies, which required the 'manipulation ... of large quantities of blood and blood products'.<sup>29</sup>

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<sup>27</sup> *ibid.*, p.2.

<sup>28</sup> Hiddlestone to EAC, 'Laboratory acquired infection of serum hepatitis', AAFB 632 WZ788 151 29/19.

<sup>29</sup> F. B. Desmond, 'Report into the Death of the Late Janet Hicks', AAFB 632 WZ788 151 29/19, p.6.

On the basis of his investigation, Desmond determined that laboratory work practices were in urgent need of review. He regarded Hicks' junior status as a contributing factor to her illness; in his opinion, the lack of qualified laboratory personnel, fragmentation of routine work and inadequate training and supervision of junior staff had increased the likelihood of her exposure to the hepatitis B virus. Moreover, he noted that senior staff did not always take the occupational hazards in the laboratory environment seriously. As an experienced pathologist, Desmond admitted that 'One of the major problems faced by laboratories the world over has been the difficulty of instilling into staff of all grades and experience a healthy respect for the handling of blood.'<sup>30</sup> In his opinion, Hicks' death was a clear indication of the need to change the prevailing attitudes towards occupational safety and to improve the standard of existing work routines.

Desmond implicated commonly used equipment, such as mouth pipettes, as potential sources of infection. He noted that when junior staff had asked more senior colleagues in the Wellington and Hutt hospital laboratories to replace mouth pipettes with safer equipment (presumably in response to Hicks' death), this request 'was met ... with the instruction to use rubber bulbs'. As Desmond explained, 'This latter ... would be possible for experienced and skilled people. However, it is not a reasonable technique ... for relatively junior staff'.<sup>31</sup> Other items in regular use, including blood collection tubes, were also linked with the risk of exposure to the hepatitis B virus. The tubes had rubber stoppers, which 'in practice, were not possible to remove without the operator's hands becoming contaminated with blood or serum'. Protective gloves were of no practical use, because 'both tube and stopper require a firm grip, and gloves are slippery'. Desmond recommended that other containers be investigated, and that automated machinery be introduced to reduce the frequent handling of potentially infectious material.<sup>32</sup>

As a result of the inquiry, Desmond developed a broader perspective on the occupational hazards of hepatitis B. He concluded that 'the further one goes into the problem the more

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<sup>30</sup> *ibid.*, p.11.

<sup>31</sup> *ibid.*, p.9.

<sup>32</sup> *ibid.*, p.4; p.12.

apparent it becomes that it is one involving the whole hospital and not solely the laboratory'. Over the nine months of his investigation, he had heard of at least four other cases of hepatitis among medical and nursing staff at Wellington and Hutt Hospitals, which led him to recommend that 'hepatitis committees' should be set up in base hospitals around the country. He urged that these committees 'should immediately draw up guide-lines [sic] for all departments concerning their part in the detection and care of high risk patients'.<sup>33</sup>

The Health Department took Desmond's recommendations seriously; after all, he had provided ample evidence of unsafe laboratory procedures and inadequate management of the risks to which health care workers were regularly exposed. On receipt of Desmond's report, Dr David Becroft, the paediatric pathologist at Auckland's Princess Mary Hospital and Chairman of the Department's Advisory Committee on Laboratory Services, prepared a memorandum on 'laboratory hygiene' for circulation to hospital board laboratories. He clearly prioritised the issue; a comprehensive set of recommendations for changes to laboratory practice was ready for distribution by mid-November 1971.<sup>34</sup> Becroft drew attention to 'the special danger that the virus of hepatitis presents to hospital laboratory workers', and emphasised the risks of 'transfer of blood or serum to the mouth during pipetting or while eating, nail biting, or smoking'. In the 'interests of the health of laboratory staff', he advised against smoking or eating in working areas and prohibited the use of mouth pipettes, 'except in specific circumstances authorised by the Pathologist-in-charge'.<sup>35</sup>

In May 1972, after consultation with the EAC, and in accordance with Desmond's advice, Hiddlestone issued a further set of recommendations that focused more broadly on the control of hepatitis in hospitals. These included careful handling of all specimens from 'high risk' patients (those with jaundice, dialysis and renal transplant patients, and those with the Australia antigen in their blood), the provision of adequate protective

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<sup>33</sup> *ibid.*, p.15.

<sup>34</sup> Becroft to Hiddlestone, AAFB 632 WZ788 151 29/19.

<sup>35</sup> *ibid.*

clothing for all hospital staff, and the establishment of a Hospital Infectious Control Committee in each hospital board district or base hospital ‘as a means of controlling hepatitis, and cross infection in general’.<sup>36</sup> Once policy makers reflected on these wider issues, they seemed to be self-evident; as the EAC observed, ‘hospital staff have always been exposed to infection and should be aware of the precautions advised’. Moreover, by emphasising the importance of ‘good housekeeping and good personal hygiene in the control of infection’, the EAC implicated the hospital environment and workers’ personal habits in hepatitis B prevention.<sup>37</sup>

While the Health Department was convinced of the importance of its policies, the urgency with which hospital boards implemented them is hard to assess. In 1974, in a circular letter to hospital boards, the Department reiterated the importance of active infection control committees, and in early 1980, complained that ‘there are still many Boards which either do not have such Committees at all, or else [they] only meet on an irregular basis and achieve minimal results’.<sup>38</sup> Furthermore, safety standards in hospital laboratories were a matter of concern throughout the 1970s. A survey conducted among Auckland laboratory staff in the early 1980s indicated that potentially hazardous work habits, such as eating and smoking in laboratories, were hard to eradicate and that hepatitis B virus infections were still occurring.<sup>39</sup>

Nevertheless, during the 1970s there was a definite shift in policy focus. Attention turned firstly from the infectious risks associated with blood transfusion to the occupational risks facing laboratory workers, then to the broader hazards of hepatitis B for all health care workers. From late 1972 onwards, prompted by the death of a local laboratory worker, policy makers looked beyond blood banks and laboratories to general hospitals, where

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<sup>36</sup> Department of Health, Circular Letter Hosp. No. 1972/90, 18 May 1972, ‘Hepatitis in Hospitals’, ZABV A1073 103a, ANZA.

<sup>37</sup> EAC, ‘Annual Report to the Board of Health for the Year Ended 30 September 1972’, AAFB 632 WZ788 151 29/19, ANZW.

<sup>38</sup> Department of Health, Circular Letter No. Hosp. 1974/189, 8 October 1974, ‘Nosocomial Infections’, ZABV A1073 95a, ANZA; Department of Health, Circular Letter No. Hosp. 1980/18, 30 January 1980, ‘Nosocomial Infection Control’, ZABV A1073 90a, ANZA.

<sup>39</sup> R. A. Anderson, D. G. Woodfield, ‘Hepatitis B virus infections in laboratory staff’, NZMJ, 95, 10 February 1982, pp.69-71.

the routine duties of a wide range of health workers were seen to increase their risk of exposure to hepatitis B virus infection.

### **The proposal to screen New Zealand health care workers in the early 1970s**

The Health Department accepted the majority of F. B. Desmond's recommendations as practical and effective ways to minimise the spread of hepatitis B virus infection in laboratories and hospitals. However, his proposal to introduce the routine hepatitis B screening of health care workers was considered more contentious. Departmental advisors were unconvinced of the need for staff screening, or of the possible benefits it might bring.

In his 1971 report to the Health Department, Desmond made strong recommendations for the routine screening of health care workers. In his opinion, 'it [was] patently obvious that adequate control of the spread of the infectious agent can be achieved only when its presence is diagnosed at the earliest opportunity'. Desmond proposed that all laboratory staff, and all medical, nursing, technical and ancillary workers employed in renal dialysis units and cardiac surgery wards should be screened for the 'Australia antigen' at monthly intervals, and that those identified as hepatitis B antigen positive should be subject to 'immediate removal from active duties and from the hospital environment'. He argued that not only would this reduce transmission rates in the short term, but regular screening would identify those staff members who had developed immunity to the virus. He regarded this group as potentially useful: 'these people could be used in high risk areas ... Truly immune people could become extremely valuable hospital personnel'.<sup>40</sup>

Desmond's views were most likely influenced by the measures implemented in the early 1970s in the UK and the US to control hepatitis B outbreaks in renal dialysis units. As Chapter Two discussed, in 1971, once a hepatitis B test became widely available, the US Centers for Disease Control (CDC) recommended regular staff and patient screening in dialysis units to prevent the spread of infection. UK health authorities took a similar approach. As Jennifer Stanton explained, UK hospital officials struggling to deal with

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<sup>40</sup> F. B. Desmond, 'Report into the Death of the Late Janet Hicks', AAFB 632 WZ788 151 29/19, pp.14-5.



severe outbreaks considered staff screening to be among the most effective measures instituted to prevent the spread of hepatitis B. Moreover, immune staff members were regarded as a potential asset, 'who should if possible be induced to return to work', while staff found to be hepatitis B carriers were excluded from working in dialysis units.<sup>41</sup>

In New Zealand, hepatitis B had been less apparent as a clinical problem, and as a consequence there was less pressure for the introduction of regular staff screening. In a letter to John Hiddlestone in November 1971, David Becroft, Chairman of the Advisory Committee on Laboratory Services, expressed general support for Desmond's recommendations, but in the matter of screening laboratory staff to detect their hepatitis B status, he was less than enthusiastic. According to Becroft, views among pathologists were 'divided' on the suggestion that screening would provide a means of measuring the efficiency of precautionary procedures, or that the removal of infected workers would reduce the spread of disease:

We would like more information on the indications for regular testing of all laboratory staff ... and in particular the need for removal of people with the antigen ... until they become negative. I am not certain who is considered at risk from these carriers and I understand that in the Auckland Blood Transfusion Service, staff who become [hepatitis B] antigen positive are not put off work.<sup>42</sup>

The Health Department referred debate on this and other issues raised by Desmond's report for consideration by the EAC. While the EAC supported the majority of Desmond's recommendations, committee members were unanimous in agreeing that there was no place for regular staff screening or removal of staff from the clinical setting. They made an unequivocal statement on the matter: 'as no action [should] follow the finding of a staff member who is positive for Australia antigen, the regular routine testing of ... staff for Australia antigen is not recommended'. The committee added that staff screening would only be acceptable in certain circumstances: 'As an indicator of the

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<sup>41</sup> J. M. Stanton, 'Health Policy and Medical Research: Hepatitis B in the UK since the 1940s', p.127.

<sup>42</sup> Becroft to Hiddlestone, AAFB 632 WZ788 151 29/19.

correctness of techniques of handling blood by laboratory staff the Director of a Laboratory may wish to test his staff from time to time but this would be done at the discretion of the Director and not as a routine procedure.’<sup>43</sup>

The committee’s views were put to the test two years later. In October 1973, Dr Brian Christmas, the Deputy Director-General of Public Health and the departmental representative on the EAC, requested advice on the management of a junior doctor who had recently contracted hepatitis B. The EAC had not altered its position; it advised that there was no need to isolate the doctor from family, staff or patients, and that he could continue in his clinical role without restrictions.<sup>44</sup>

As early as 1971, then, the EAC took a firm stand against the routine hepatitis B screening of health care workers and the imposition of practice restrictions. While there was some support for screening among senior members of the medical profession, the Health Department, which was under no immediate pressure to consider screening as an infection control measure, was willing to accept the EAC’s advice on this matter. The committee’s stance set an important policy precedent; as Chapter Nine will discuss, departmental policy on hepatitis B infected health care workers remained largely unchanged throughout the 1970s and 1980s, despite the emergence of another blood borne disease, Acquired Immune Deficiency Syndrome (AIDS), in the early 1980s.

### **The international debate on hepatitis B infected health care workers in the 1970s**

In the early 1970s, when the introduction of the hepatitis B test first presented the opportunity to identify asymptomatic carriers, international opinion was divided on the issue of hepatitis B infected health care workers. While prominent doctors in the UK supported the exclusion of hepatitis B carriers in areas where patients were highly susceptible to hepatitis B virus infection, US hepatitis experts argued that further research was required to determine the level of risk that carriers posed to patients.

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<sup>43</sup> EAC minutes, 23 September 1971, AAFB 632 WZ788 151 29/19, ANZW.

<sup>44</sup> EAC minutes, 11 October 1973, AAFB 632 WZ788 151 29/19, ANZW.

In the US, the uncertainties around person-to-person transmission of the hepatitis B virus were considered a major obstacle to the development of policies for infected health care workers. In a 1971 article, virologist Dr Harvey Alter, a leading advocate for hepatitis B screening in US blood banks, and Dr Thomas Chalmers, Director of the Clinical Center at the National Institutes of Health, acknowledged that health care workers presented a ‘special problem’, because they had both ‘increased exposure to the virus and a potentiality for spread to their patients’.<sup>45</sup> Nevertheless, they asked whether the scant data available on hepatitis B transmission supported the imposition of stringent practice restrictions on hepatitis B carriers:

Can the data on the minute dose required for ... [transmission of the hepatitis B virus] be applied to those in the health-delivery professions who have an opportunity to transmit their [blood] to patients by cutting or pricking themselves in the course of surgical or dental procedures? ... Is the danger great enough to proscribe their close contact with patients?<sup>46</sup>

While Alter and Chalmers supported hepatitis B screening for health care workers, this was to enable carriers to be advised of the need for careful hand washing and the use of gloves during procedures that presented a potential risk to their patients. In their opinion the problem of the hepatitis B infected health care worker was likely to be larger than previously imagined: the ‘carrier rate in surgeons, dentists and related health-care personnel may be as high as 1 to 2 per cent’. As a consequence, they argued that ‘the implications of removing trained personnel from patient contact [were] too broad, the number involved too great, and the psychosocial effect too devastating to base decisions on anything but conclusive data’. To clarify the risks of transmission, Alters and Chalmers proposed ‘careful epidemiologic [sic] studies based on widespread testing ... and the prospective follow up of professional contacts’.<sup>47</sup> Their views proved highly influential in the US, where further research was promoted as the most appropriate means of addressing this contentious area of health policy.

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<sup>45</sup> T. C. Chalmers, H. J. Alter, ‘Management of the asymptomatic carrier of the hepatitis-associated (Australia) antigen’, *NEJM*, 285, 11, 9 September 1971, p.613.

<sup>46</sup> *ibid.*, p.615.

<sup>47</sup> *ibid.*

During the next four years, however, no research was undertaken. Notwithstanding the professional issues involved, there were practical problems in conducting prospective patient research. While prevalence studies were relatively simple to conduct among blood donors and hospital workers, prospective studies among patients were considerably more complex and costly to conduct. Hepatitis B has a six week to six month incubation period, and patients often disperse widely after medical or surgical interventions. Nevertheless, in spite of these difficulties of following up patient contacts for lengthy periods, prospective studies were seen as the way forward by the US medical profession.

In the UK, on the other hand, the renal dialysis outbreaks continued to influence attitudes towards infected health care workers. Expert opinion favoured the use of selective screening, and practice restrictions. An editorial in the *British Medical Journal* in 1974, for example, proposed staff screening in clinical areas known to be implicated in hepatitis B transmission:

... it is within the hospital that the chances of cross-infection are greatest, particularly in the areas of blood transfusion and renal medicine. All personnel must be screened at regular intervals for the antigen. Staff members found to be positive will have to be found other work ...<sup>48</sup>

During the 1970s, the reports of the WHO Expert Committee on Viral Hepatitis, which represented the views of leading hepatitis researchers, traced the evolving debate. The 1973 report stated that members of hospital staff who were hepatitis B carriers were 'not necessarily a hazard' to patients, except in areas of known risk. The committee concluded that 'Careful studies [were] needed ... to resolve this matter'.<sup>49</sup> It recommended that carriers should 'use precautions in their professional activities' (presumably hand washing and the use of gloves as these were not specified), and that staff in dialysis and kidney transplantation units should be screened 'regularly'.<sup>50</sup> Until transmission studies

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<sup>48</sup> Anon., 'Editorial: What shall we with the HBsAg carrier?', *British Medical Journal*, 5942, 23 November 1974, pp.427-8.

<sup>49</sup> WHO, *Report of the WHO Scientific Group on Viral Hepatitis: Technical Report Series No. 512*, p.35.

<sup>50</sup> *ibid.*, p.43; p.45.

were undertaken, the experts advised that ‘it would be prudent to exclude such carriers [from these units]’.<sup>51</sup>

The emphasis on renal transplant and dialysis-related infection in the 1973 report was not surprising; Professor B. P. Marmion, a bacteriologist at the Edinburgh University Medical School and a member of the WHO committee, had been personally involved in the management of the 1969 outbreak at the Edinburgh Royal Infirmary. In 1975, by contrast, the WHO committee took a stronger stance on the rights of carriers to continue in professional practice, declaring that ‘there is no firm evidence that [hepatitis B] positive health care staff present any potential hazard either to patients under their care or to the general public’.<sup>52</sup> It is worth noting, however, that compared with the 1973 committee which had two UK and two US members out of a group of eight international appointees, the 1975 committee was dominated by Americans (five of its eight members were from the US).<sup>53</sup>

The 1975 report dropped all reference to staff screening and the exclusion of carriers from high risk clinical areas. It did, however, suggest a cautionary approach, stating that ‘at present there is no evidence that carriers belonging to the medical or other professions in close contact with the general population routinely present a hazard, provided they take special precautions in their professional activities’.<sup>54</sup> The types of precautions and the professional activities that might lead to transmission were unclear, perhaps because these were still a matter of expert opinion, rather than scientifically derived ‘facts’. To delineate the risk that carriers presented to their patients and social contacts, the committee once again recommended research studies ‘to detect whether and under what specific conditions transmission of infection occurs’.<sup>55</sup>

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<sup>51</sup> *ibid.*, p.35.

<sup>52</sup> WHO, *Viral Hepatitis: Report of the WHO Expert Committee on Viral Hepatitis: Technical Report Series No. 570*, Geneva, 1975, p.11.

<sup>53</sup> Despite the apparent imbalance in its membership, the frontispiece of the 1975 WHO report stated that ‘The selection of members of international groups is based primarily on their ability and technical expertise, with due regard to adequate geographical distribution.’

<sup>54</sup> *ibid.*, p.49.

<sup>55</sup> *ibid.*, p.50.

The hesitation evident in the WHO recommendations was most likely the result of three confirmed instances of health care worker to patient transmission of hepatitis B reported in the US between 1972 and 1974. In the first, eleven patients were infected by a surgical nurse who had developed an acute hepatitis B virus infection as the result of an occupational injury.<sup>56</sup> This case did nothing to illuminate the factors that contributed to patient risk; the nurse ‘did not routinely dress wounds or replace intravenous catheters’, and there appeared to be ‘no breaks in her sterile technique’.<sup>57</sup> Two further outbreaks occurred in 1974, the largest of which involved 53 patients traced to an oral surgeon.<sup>58</sup> Two of his patients became carriers while one died of fulminant liver failure.<sup>59</sup> By way of response, the CDC, which carried out the investigation, recommended ‘a large-scale study that would screen dental personnel at regular intervals for the presence of [hepatitis B antigen]’.<sup>60</sup>

While epidemiological studies might prove useful for policy makers, however, they had the potential to reveal higher levels of hepatitis B transmission from carriers to their patients than initially anticipated. This was a disturbing prospect for health care workers, particularly surgeons and dentists, who were known to have a high risk of exposure to the disease.<sup>61</sup> In the event, the seminal research on hepatitis B transmission in health care settings did not focus on either of these groups. When Harvey Alter initiated a prospective study at the US National Institutes of Health in 1974, he recruited two physicians and a nurse who were hepatitis B carriers, a food handler with recently acquired hepatitis B virus infection, and a doctor in the incubation phase of acute

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<sup>56</sup> R. A. Garibaldi, C. M. Rasmussen, A. W. Holmes, M. B. Gregg, ‘Hospital-acquired serum hepatitis: report of an outbreak’, *JAMA*, 219, 12, 20 March 1972, pp.1577-80.

<sup>57</sup> *ibid.*, p.1579.

<sup>58</sup> M. L. Levin, W. C. Maddrey, J. R. Wands, A. I. Mendeloff, ‘Hepatitis B transmission by dentists’, *JAMA*, 228, 27 May 1974, pp.1139-40; D. Rimland, W. E. Parkin, ‘An outbreak of hepatitis B traced to an oral surgeon’, *Gastroenterology*, 67, 4, 1974, p.822.

<sup>59</sup> *ibid.*

<sup>60</sup> M. L. Levin, W. C. Maddrey, J. R. Wands, A. I. Mendeloff, ‘Hepatitis B transmission by dentists’, p.1140.

<sup>61</sup> The earliest report suggesting that surgeons were at high risk of exposure to the hepatitis B virus was published in 1973. By the late 1970s, prevalence studies indicated that over a quarter of US surgeons and pathologists had been infected with the disease. See for example, J. L. Rosenberg, D. P. Jones, L. R. Lipitz, J. B. Kirsner, ‘Viral hepatitis – an occupational hazard to surgeons’, *JAMA*, 223, 22 January 1973, pp.395-400; A. E. Denes, J. L. Smith, J. E. Maynard, I. L. Doto, K. R. Berquist, A. J. Finkel, ‘Hepatitis B infection in physicians’, *JAMA*, 239, 16 January 1978, pp.210-2.

hepatitis. Of their 228 contacts followed for six to nine months, none developed clinical infection or positive serology.<sup>62</sup>

Whether Alter and his team deliberately chose ‘low risk’ research subjects is not known, however, they did acknowledge that their study was not representative of the professional groups considered most likely to transmit infection. Nevertheless, from their findings, Alter and his colleagues concluded that policies restricting the professional practice of infected health care workers were unnecessary, unless they were implicated in cases of direct transmission:

... there is no current scientific basis for determining the need to restrict the professional activities of [carriers] ... Such restrictions would often result in permanent occupational rejection of the health worker and in total disruption of career goals with far-reaching economic and psychologic [sic] effects ... We believe that current evidence does not warrant restriction of the professional activities of [hepatitis B] positive health-care personnel.<sup>63</sup>

Their stance had the support of leading figures in hepatitis research. Dr James Mosley, former Head of the Hepatitis Division at the CDC, for example, argued that only those workers who had been implicated as a likely source of infection should be barred from direct health care. He warned of ‘reciprocal responses’ against patients if infected doctors and dentists were denied employment in their chosen careers: ‘the transplant team that will not accept patients who are carriers or the dentist who refuses care to patients with a history of hepatitis’.<sup>64</sup> Further, Dr Baruch Blumberg, the US geneticist whose research team first discovered the hepatitis B antigen, cautioned against creating a ‘stigmatized “class”’ of carriers when the ‘hazard to the public had not been defined’.<sup>65</sup>

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<sup>62</sup> H. J. Alter, T. C. Chalmers, B. M. Freeman, J. L. Lunceford, T. L. Lewis, P. V. Holland, P. A. Pizzo, P. H. Plotz, W. J. Meyer, ‘Health-care workers positive for hepatitis B surface antigen: are their contacts at risk?’, *NEJM*, 292, 9, 27 February 1975, pp.454-7.

<sup>63</sup> *ibid.*, p.457.

<sup>64</sup> J. W. Mosley, ‘The HBV Carrier – A New Kind of Leper?’, *NEJM*, 292, 9, 27 February 1975, pp.477-8.

<sup>65</sup> B. S. Blumberg, ‘The bioethical dilemma of the hepatitis carrier’, *P & S Journal*, Winter 1977, p.29.

Despite the convergence of expert opinion, however, the issue caused some disquiet. One doctor questioned the apparent contradiction between Alter's study and a paper presented by the CDC on the 1974 case of the oral surgeon, which clearly stated medical carriers could pose a risk to the public.<sup>66</sup> 'What should I tell my patients who are carriers and who are in the health-care field?' he wrote to the *New England Journal of Medicine*.<sup>67</sup> In response, Alter, Chalmers and Dr Paul Holland, Director of the National Institutes of Health Blood Bank, stated that the 'conclusion [of their study] was an interim decision' and that all health professionals would be implicated if the medical profession were to take the route of restricting carriers from patient contact:

We have not claimed to have proved the safety of [hepatitis B positive] health workers ... What we stated was that the routine restriction of all positive health personnel is a decision of enormous magnitude markedly affecting the lives of a large number of professional people as well as the lives of those who might enter the health professions in the future ... to be fair, it would necessitate universal and enforced screening of all health personnel.<sup>68</sup>

No other prospective studies were completed during the 1970s, in the US or elsewhere. US historian William Muraskin later argued that the medical profession colluded to prevent the issue being brought the attention of the unsuspecting public, and that the profession's 'wait-and-see' attitude prevented open debate about a 'public health crisis'.<sup>69</sup> He castigated doctors for relying on the results of Alter's 1975 study, which was widely cited in support of a voluntary, rather than mandatory, approach to screening healthcare workers. As Muraskin explained, the US dominated basic hepatitis research during the 1970s, and the views of leading US researchers were highly influential; 'the position on carriers espoused in the United States was echoed abroad'.<sup>70</sup> To prove his point, Alter's research was quoted in a 1977 article in the *New Zealand Medical Journal*

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<sup>66</sup> D. Rimland, W. E. Parkin, 'An outbreak of hepatitis B traced to an oral surgeon', p.822.

<sup>67</sup> M. K. Gooding, 'Letter to the Editor: Risk to contacts of HBsAg carriers', *NEJM*, 292, 20, 15 May 1975, p.1079.

<sup>68</sup> H. J. Alter, P. V. Holland, 'Letter to the Editor: Risk to contacts of HBsAg carriers', *NEJM*, 292, 20, 15 May 1975, p.1079.

<sup>69</sup> W. Muraskin, 'The silent epidemic: The social, ethical and medical problems surrounding the fight against hepatitis B', p.285.

<sup>70</sup> *ibid.*, p.295.



which took a stance against routine staff screening: '[This] is not carried out because of current indecision over what to do with these people if found positive. Alter ... suggested that restriction of [hepatitis B] carriers is not warranted'.<sup>71</sup>

Muraskin considered US views were so persuasive that 'there is no reason to believe the WHO recommendations were based on research independent of the limited American studies'.<sup>72</sup> Indeed, the 1977 report of WHO expert committee on viral hepatitis, which described transmission of hepatitis B from health care workers to their patients as 'rare', referenced Alter's 1975 study. The 1977 report went on to state that 'the available information shows that health care personnel are at greater risk of contracting hepatitis B than *vice versa* and that such personnel do not usually transmit the disease to their patients'. Moreover, the occupational categories and work areas considered at 'excess risk of hepatitis B infection' were expanded to include doctors, dentists, nurses, cancer wards and surgical intensive care units.<sup>73</sup>

Whether this was a case of collusion, as Muraskin argued, or, as appears more likely, a means of circumventing professional issues that were too contentious and far-reaching for policy makers to consider, the WHO's approach found widespread favour. While its recommendations served professional agendas, equally, the complications and expense of screening health care workers acted as a powerful disincentive to the introduction of restrictive employment policies. Jennifer Stanton concluded that the UK Advisory Group on Hepatitis recommended against routine staff screening in 1981, 'presumably [because they] foresaw great problems if they counselled a policy of screening staff and removing such a significant number of carriers from "hands-on" work in the NHS'.<sup>74</sup> Like Mosley, they regarded the risk of transmission to patients as 'rare', and believed that if screening

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<sup>71</sup> J. L. Faoagali, S. A. Young, 'Distribution of Anti HBs in Christchurch hospital staff', NZMJ, 87, 22 February 1978, p.123.

<sup>72</sup> W. Muraskin, 'The silent epidemic: The social, ethical and medical problems surrounding the fight against hepatitis B', p.295.

<sup>73</sup> WHO, *Advances in Viral Hepatitis: Report of the WHO Expert Committee on Viral Hepatitis: Technical Report Series No. 602*, Geneva, 1977, pp.45-6.

<sup>74</sup> J. M. Stanton, 'Health Policy and Medical Research: Hepatitis B in the UK since the 1940s', p.219.

was imposed as a professional requirement, surgeons might demand reciprocal screening of patients, ‘which would be costly and perhaps politically embarrassing’.<sup>75</sup>

During the early 1970s therefore, the views of US researchers gradually dominated over those of other international hepatitis experts. By the mid-1970s, there was widespread consensus that the risks to patients from hepatitis B infected health care workers were too small to warrant the imposition of professional practice restrictions. Health authorities in Western countries including the US, the UK, and New Zealand came to focus almost entirely on the ‘at risk’ status of health care workers, while minimising the potential risks of hepatitis B transmission to patients.<sup>76</sup>

### **Compensation for occupationally-acquired hepatitis B in the 1970s**

In the early 1970s, recognition that health care workers were at occupational risk of exposure to the hepatitis B virus opened the way for work-related compensation claims. In the US, compensation was paid to the first reported case of occupationally-acquired serum hepatitis, but it was forward in this regard; it was the mid-1970s before hepatitis B was scheduled as an ‘industrial’ disease in the UK, and in New Zealand the Accident Compensation Commission (ACC) was still quibbling over the link between occupational exposure and hepatitis B virus infection in 1976.<sup>77</sup>

In the US in 1949, in the first documented case of occupationally-acquired hepatitis B, wages compensation was awarded to a phlebotomy nurse who worked at a New York blood bank. Despite the difficulty of verifying the exact circumstances of her exposure to the infectious agent, the New York State Workmen’s Compensation Board determined there was a causal relationship between the nurse’s illness and her employment, and

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<sup>75</sup> *ibid.*, p.220.

<sup>76</sup> See for example the views expressed in 1978 by Dr James Maynard, Head of the Hepatitis Division of the CDC in a chapter entitled ‘Viral hepatitis as an occupational hazard in the health care profession’, in G. N. Vyas, S. N. Cohen, and R. Schmid, *Viral Hepatitis: A Contemporary Assessment of Etiology, Epidemiology, Pathogenesis and Prevention*, p.322.

<sup>77</sup> The Accident Compensation Act 1972 provided for the introduction of the Accident Compensation Commission (ACC), which from April 1974 administered a ‘no-fault’ accident compensation scheme, covering both work-related and non-work injuries. For an overview of the development of ACC in New Zealand see ‘A Brief History of ACC’, online, nd, available at: [http://www.acc.co.nz/about-acc/overview-of-acc/introduction-to-acc/ABA00004#P25\\_2938](http://www.acc.co.nz/about-acc/overview-of-acc/introduction-to-acc/ABA00004#P25_2938) (5 September 2009).

made an award in her favour.<sup>78</sup> By 1948, most US states had some form of workman's compensation in place, and two subsequent reports of work-related hepatitis B in the US in the early 1950s also discussed financial recompense for affected laboratory and blood bank workers.<sup>79</sup>

In the UK, hepatitis B did not emerge as an occupational issue until the renal dialysis outbreaks brought the hazards of the disease into focus. As discussed earlier in this chapter, the risks had been present but not recognised by health officials or by workers themselves. An editorial in the *British Medical Journal* in 1976 declared that in spite of sporadic reports of hepatitis among laboratory workers for 25 years, '[it] did not appear to be a serious occupational hazard in Britain until laboratory workers became affected by extensive outbreaks of viral hepatitis in haemodialysis units'.<sup>80</sup>

UK laboratory workers, who by the early 1970s considered themselves to be at high risk of exposure to hepatitis B, were active in promoting its official acceptance as an occupational disease. As Jennifer Stanton explained, 'the union that represented most blood laboratory technicians, the Association of Scientific, Technical and Managerial Staffs ... successfully campaigned in the mid-1970s for hepatitis B to be scheduled as an industrial disease'.<sup>81</sup> Despite the union's success, however, definite limits were applied to worker compensation. In view of the long incubation period of the disease, and the difficulties of pinpointing the source of infection, the UK Department of Health and Social Services was reluctant to extend cover beyond those health care workers who had 'close and frequent' contact with blood or blood products. This excluded many health professionals who were at risk of exposure to the virus during their routine work, and also prevented members of allied services such as the police, ambulance officers and mortuary

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<sup>78</sup> The nurse had frequent exposure to blood during her daily duties. For example, re-sharpening transfusion needles was one of her regular tasks in the blood bank. S. Leibowitz, L. Greenwald, I. Cohen, J. Litwins, 'Serum hepatitis in a blood bank worker', pp.1331-3.

<sup>79</sup> C. Kuh, W. E. Ward, 'Occupational virus hepatitis: An apparent hazard for medical personnel', pp.631-5; M. L. Trumbell, D. J. Greiner, 'Homologous serum hepatitis: an occupational hazard to medical personnel', pp.965-7.

<sup>80</sup> Anon., 'Hepatitis in clinical laboratories', *British Medical Journal*, 2, 6039, 2 October 1976, pp.778-9.

<sup>81</sup> J. M. Stanton, 'Health Policy and Medical Research: Hepatitis B in the UK since the 1940s', p.211.

workers from making claims. Nevertheless, as Stanton made clear, the decision was seen as an important step forward for health care workers.<sup>82</sup>

In New Zealand, the advances made in the UK prompted local doctors to ask the Health Department to consider serum hepatitis as a compensatable condition. In early 1975, Dr J. Cleminson, Medical Superintendent-in-Chief of the Otago Hospital Board, wrote to the Health Department on behalf of his medical staff to clarify the official stance on worker compensation. Receiving no response, Cleminson wrote again a year later to Dr R. Dickie, Director of the Hospitals Division, asking for the official position on the issue 'in view of the rulings given in Britain that viral hepatitis is an industrial disease'.<sup>83</sup> Dickie put Cleminson's request to the EAC for consideration, so that 'Hospital Staffs may know where they stand on this matter'.<sup>84</sup>

The EAC was firmly in favour of health care workers' rights to compensation. Its membership was substantially unchanged from the early 1970s, so that the committee was well-versed in the occupational risks of hepatitis B. Furthermore, the EAC clearly considered health care workers to be the primary risk group for the disease.<sup>85</sup> After a lengthy discussion at its meeting in March 1976, it recommended that serum hepatitis should be regarded as a compensatable disease if contracted by anyone working within the health services. However, the EAC was aware that its advice was subject to the rulings of the ACC, which had been set up in 1974 to administer a 'no-fault' compensation system for both work-related and non-work injuries.<sup>86</sup>

As the EAC had anticipated, the ACC took a narrower position on industrial compensation. Each case was considered as to whether it was accidental, and whether it was due to the nature of the claimant's employment. While accidental acquisition of serum hepatitis in a hospital or surgery appeared to meet these requirements, the ACC did

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<sup>82</sup> *ibid.*, pp.210-1.

<sup>83</sup> Cleminson to Dickie, 22 January 1976, 'Serum Hepatitis', AAFB632, W4914 45 29/19(1), ANZW. The previous letter was discussed by Cleminson in his correspondence with Dickie.

<sup>84</sup> Boyd to Cleminson, 28 June 1976, 'Serum Hepatitis', AAFB632, W4914 45 29/19(1), ANZW.

<sup>85</sup> EAC minutes, 1960-1983, AAFB 786 W3045/8, ANZW.

<sup>86</sup> EAC minutes, 23 March 1976, AAFB 786 8, ANZW.

not take this view. In 1975, compensation was awarded to an Auckland dentist, on the grounds that he used a high speed drill, which exposed him to an ‘infective aerosol spray’.<sup>87</sup> Further, the 1976 ACC annual report stated that hepatitis B was not necessarily compensatable if acquired by hospital staff, and that compensation would only be awarded to dentists who used high speed drills.<sup>88</sup>

With the increased emphasis on their status as a high risk group, health care workers were understandably anxious about the standpoint taken by the ACC on occupationally-acquired hepatitis B. In 1977, Dr Joan Faoagali, a microbiologist at Christchurch Hospital, wrote that ‘staff in the highest risk areas were [already] concerned at the risk of contracting hepatitis B that they faced. These feelings were accentuated following the [1976] decisions by the Accident Compensation Commission’.<sup>89</sup> Faoagali, who had already undertaken several surveys of hepatitis B prevalence in the Canterbury region, took a proactive approach towards compensation claims by offering Christchurch Hospital staff the opportunity to be tested for hepatitis B, so that their records were available for future reference. In this way, she explained, ‘evidence of past exposure to, or carriage of [the hepatitis B antigen], would provide objective evidence for the Accident Compensation Commission [if a compensation claim was lodged by a hospital employee]’.<sup>90</sup>

Faoagali revealed widespread exposure to the hepatitis B virus among Christchurch health care workers. Of 338 hospital employees tested, nearly a quarter (22.4 per cent) of medical staff, 10 per cent of nursing staff, 11.4 per cent of the laboratory staff, and over a third (36.4 per cent) of the dental staff tested had antibodies to the virus. The high rates of infection among the board’s doctors and dentists (12 of 77 had positive hepatitis B serology) were consistent with the results of overseas studies, which indicated that the prevalence of infection among doctors and dentists was three to four times higher than

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<sup>87</sup> ‘Hepatitis – Dentist’, Review hearing by Hearing Officer, 9 December 1975, reported in *N.Z. Sanitarian*, 31, 3, March 1977, pp.77-8.

<sup>88</sup> Accident Compensation Commission New Zealand, *ACC Report*, Wellington, 1976, p.22, cited in J. L. Faoagali and S. A. Young, ‘Distribution of Anti HBs in Christchurch hospital staff’, pp.121-3.

<sup>89</sup> *ibid.*, p.121.

<sup>90</sup> *ibid.*

among the general population. While infection rates among laboratory staff were relatively low, Faoagali argued that this was the result of a ‘continual awareness of the problem’, and the use of strict safety precautions in the Christchurch Hospital laboratory.<sup>91</sup>

Faoagali’s approach reflected the increasing importance of hepatitis B testing; from the mid-1970s the ACC relied heavily on test results when assessing work-related claims for viral hepatitis. Health workers quickly grasped the importance of hepatitis B testing to prove work-related claims. As one Auckland surgeon observed:

If you documented an injury as work-related, it was compensatable. So, if you had a needlestick injury or something similar, and if the patient tested hepatitis B positive and you were negative, but subsequently became positive, then that was considered a work-related accident, and was compensatable by ACC ... People were aware of the compensation aspect. Whereas if you contracted hepatitis B and couldn’t relate it to a work accident, tough luck.<sup>92</sup>

Hence, in the mid-1970s New Zealand health care workers followed the lead of UK laboratory workers in demanding compensation for work-related hepatitis B virus infections. However, the ACC, which appeared to be influenced by the stance taken by the UK health authorities, was unwilling to extend compensation except under certain closely prescribed circumstances. New Zealand health care workers, confident that no practice restrictions would be placed on hepatitis B carriers, were willing to undergo testing to provide serological evidence for work-related claims.

### **The prevalence of hepatitis B virus infection in New Zealand in the 1970s**

In the early 1970s, when testing for hepatitis B became widely available, the New Zealand medical profession assumed that local prevalence patterns would closely resemble those of other western countries. As a result, the primary objective of most prevalence studies was to investigate groups of adults already known to be at high risk of infection as a result of their occupations or their anti-social activities in the US or UK. In

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<sup>91</sup> *ibid.*, p.123.

<sup>92</sup> Anonymous source.

addition, general practitioners were slow to adopt the hepatitis B test as a routine diagnostic tool, so that medical perceptions of the prevalence of the disease remained largely unchanged over the 1970s.

In September 1971, serum hepatitis became a notifiable disease in New Zealand. In a brief report on this change in procedure, the *New Zealand Medical Journal* noted that although it was 'formerly associated with blood transfusion only, serum hepatitis has gained greater significance with increasing and varying use of blood in hospitals and also with the habit by drug addicts of sharing syringes'.<sup>93</sup> The report concluded that 'one district has reported several cases from [drug addiction] in recent months. Early notification and investigation are thus necessary to allow appropriate control measures to be taken'.<sup>94</sup>

In the early 1970s, New Zealand health authorities, like those of other Western countries, regarded hepatitis B as a disease primarily transmitted in health care settings. Contaminated needles were known to be a source of infection, and the increasing evidence of hepatitis B among injecting drug users informed broader social concerns. By the late 1960s, most Western countries had introduced drug dependence clinics, and advisory groups on drug addiction.<sup>95</sup> While the introduction of the hepatitis B test, which enabled doctors to differentiate between serum and infectious hepatitis, was an obvious factor in the change in notification procedures, concerns over the increasing use of illicit drugs and the occupational risks of the virus also played a part. In its annual report in

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<sup>93</sup> Anon., 'News: Hepatitis (infectious or serum)', *NZMJ*, 80, October 1971, p.267.

<sup>94</sup> *ibid.*

<sup>95</sup> In New Zealand, a Health Department Committee on Drug Dependency and Drug Abuse was established in the 1960s, to gather information and provide advice to the department on this issue. Department of Health, Circular Memorandum No. 1970/134, 7 July 1970, 'Board of Health Report on Drug Dependency and Drug Abuse in New Zealand', ZABV A1073/106a/1, ANZA. Furthermore, the Medical Association of New Zealand's submission on the 1974 Government White Paper 'A Health Service for New Zealand' included the recommendation that 'doctors be encouraged to study the increasing problems of alcohol and drug addiction'. MANZ, 'An Improved Health Service for New Zealand', 1975, p.9. At an international level, the WHO issued recommendations in 1973 in response to 'widespread concern about the use of dependence-forming drugs'. WHO, *Youth and Drugs: Technical Report Series No. 516*, Geneva, 1973.

1972, the Health Department reported that 13 cases of serum hepatitis had been notified, 'many among drug users'.<sup>96</sup>

The Health Department did not anticipate that there would be a large number of cases notified under the category of serum hepatitis. On the contrary, infectious hepatitis, or hepatitis A, was the most commonly notified communicable disease in New Zealand, and there was no expectation that this situation would change in the short term. In the 1950s and 1960s, New Zealand, Australia, and many other Western countries experienced extensive community outbreaks of infectious hepatitis.<sup>97</sup> In 1959, the Health Department noted in its annual report that 'this disease continues to gain ground and is one of our most serious public health problems'.<sup>98</sup> From 1961 to 1971, 3000 to 5000 cases were notified to the Department annually.<sup>99</sup>

As a consequence, by the 1970s, GPs were more likely to assume that community-acquired jaundice was hepatitis A, which is spread by the faecal-oral route, than hepatitis B. The first indication that the epidemiology of hepatitis B in New Zealand might differ from that of other Western countries came from blood bank data, as discussed in Chapter Two. These statistics revealed a much higher prevalence of hepatitis B carriage among Maori and Pacific blood donors than among their European counterparts. Similarly, a survey in a borstal institution in the Waikato region found substantially higher rates of hepatitis B carriage among Maori inmates than among non-Maori. However, these reports were published in specialist medical journals with limited circulations.<sup>100</sup> During the early 1970s, GPs continued to notify most cases of community-acquired hepatitis as hepatitis A rather than hepatitis B.

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<sup>96</sup> AJHR, 1972, H.31, p.25.

<sup>97</sup> At its meetings in 1953 and 1964, the WHO Expert Committee on Viral Hepatitis regarded infectious rather than serum hepatitis to be the greater problem worldwide. WHO, *Expert Committee on Hepatitis: First Report: Technical Report Series No. 62*, p.3; WHO, *Expert Committee on Hepatitis: Second Report: Technical Report Series No. 285*, p.5; C. R. Lucas, 'Hepatitis in Victoria'.

<sup>98</sup> AJHR, 1959, H. 31, p.20.

<sup>99</sup> AJHR, 1973, E.10, p.122.

<sup>100</sup> P. B. Booth, J. M. Staveley, 'Hepatitis-associated antigen testing by the New Zealand Blood Transfusion Services'; C. M. Boveington, 'The incidence of hepatitis associated antigen in the Waikato'.



Unsurprisingly, transfusion specialists were the first to challenge the accuracy of the notifications for viral hepatitis. In early 1975, the Transfusion Advisory Committee discussed a summary of hepatitis B cases notified to the Health Department in the years 1973 to 1974. Where antigen testing was taking place, cases of hepatitis B were rising, calling into question the number of cases that were being misdiagnosed:

There is a marked increase in [hepatitis B] notifications in 1974 compared with 1973; most of the additional cases being reported from Christchurch ... It is clear that either cases are not being diagnosed or known cases are not being notified. It was considered that the high returns from Christchurch reflected a more efficient testing programme in cases of hepatitis and that elsewhere cases were just not being recognised.<sup>101</sup>

In 1976, a review of 73 hepatitis cases notified to the Christchurch Medical Officer of Health also suggested serious anomalies in the notification of viral hepatitis. The authors, Joan Faoagali and D. Gidall, a Christchurch City Council Health Inspector, found that 21 hepatitis B cases had been wrongly notified as hepatitis A, almost a third of the total notifications in this category. Faoagali and Gidall strongly recommended that doctors should consider testing for hepatitis B as a routine diagnostic procedure.<sup>102</sup> Faoagali, who was a member of the EAC from 1981 to 1983, took a particular interest in the prevalence of hepatitis B in the Canterbury region, conducting five hepatitis B surveys during the mid-1970s among different sub-groups in the local population. Nevertheless, her studies reflected the focus of overseas research by concentrating primarily on adults with known risk factors rather than on community transmission of the virus.<sup>103</sup>

The Health Department, too, was focused on the prevalence of hepatitis B virus infection among adults, particularly those in the health care professions. The departmental report to

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<sup>101</sup> TAC minutes, 6-7 March 1975, private papers, J. B. Howie.

<sup>102</sup> J. L. Faoagali, D. Gidall, 'Hepatitis B surface antigen in notified cases of viral hepatitis', pp.50-3.

<sup>103</sup> J. L. Faoagali, P. B. Booth, 'Hepatitis B surface antigen and antibody among Samoans living in Christchurch', pp.278-80; J. L. Faoagali, S. A. Young, 'HbsAg and Anti-HBs in staff and patients of a psychopaedic hospital', NZMJ, 85, 25 May 1977, pp.416-20; J. L. Faoagali, S. A. Young, 'Distribution of Anti HBs in Christchurch hospital staff', pp.121-3; J. L. Faoagali, 'Hepatitis B serology in 1000 VD clinic attenders', NZMJ, 96, 28 October 1983, pp.297-9; J. L. Faoagali, 'Hepatitis B markers in Canterbury dental workers: a seroepidemiological survey', NZMJ, 99, 22 January 1986, pp.12-4.

the 1977 WHO Interregional Seminar on Viral Hepatitis, for example, noted that the prevalence of hepatitis B in New Zealand has been studied in several high risk occupational groups.<sup>104</sup> This report, which pondered over the decline in notifications for hepatitis A and the corresponding rise in notifications for hepatitis B, suggested that this might 'reflect a growing awareness of the disease and the improved sensitivity of the tests used'.<sup>105</sup> In fact, during the mid-1970s, little use was made of the hepatitis B test as a diagnostic tool. Between 1974 and 1978 there were over 13,000 notifications of acute hepatitis in New Zealand, but of these only 930 (seven per cent) were for hepatitis B.<sup>106</sup> Established views were hard to shift, and even though vast quantities of new data were being generated by hepatitis B researchers worldwide, these data appeared to support rather than challenge medical perceptions of the disease.

From the early 1970s, when hepatitis B became a rapidly expanding field of scientific research, epidemiological surveys revealed that hepatitis B was a disease of global proportions. An estimated 120 million people were estimated to be hepatitis B carriers.<sup>107</sup> However, the distribution of the disease differed significantly between 'first' and 'third world' countries. In Asia, Sub-Saharan Africa and the Pacific, between five and twenty per cent of the population were hepatitis B carriers compared with less than one per cent in the US, UK, Australia, and Northern Europe.<sup>108</sup> In less developed countries, infection was frequently acquired in infancy and early childhood. In Western countries, in all but unusual circumstances, hepatitis B was a disease of adulthood. Whereas children in Western societies were rarely infected by the virus, in many Asian, African and Pacific communities, hepatitis B was a major public health problem that affected people from birth to old age.

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<sup>104</sup> WHO, *Report of an Interregional Seminar on Viral Hepatitis, 28 November-1 December 1977, Lumpur, Malaysia*, ABQU 6783 W4451/1 1/2/2, ANZW.

<sup>105</sup> *ibid.*

<sup>106</sup> T. Johnstone, 'Notified viral hepatitis in New Zealand', *NZMJ*, 92, 13 August 1980, pp.85-91.

<sup>107</sup> The level of research activity was intense; according to the report of the 1973 WHO Expert Committee on Viral Hepatitis, 'new information [wa]s appearing almost daily'. WHO, *Viral Hepatitis: Report of the WHO Expert Committee on Viral Hepatitis: Technical Report Series No. 512*, p.8.

<sup>108</sup> O. Sobeslavsky, 'HBV as a global problem', in G. N. Vyas, S. N. Cohen, and R. Schmid, *Viral Hepatitis: A Contemporary Assessment of Etiology, Epidemiology, Pathogenesis and Prevention*, p.348.

In mid-1977, a letter published in the *New Zealand Medical Journal* gave the first indication that prevalence rates among New Zealand children might differ from those of other ‘first world’ countries. Alexander Milne, the Charge Laboratory Technologist at Whakatane Hospital, reported the results of an investigation into two concurrent outbreaks of viral hepatitis in an Eastern Bay of Plenty community. Of the 40 cases found to be hepatitis B positive, 25 were among children under the age of 15 years. At this early stage, Milne did not press the point that it was children who were infected, rather, he argued for the use of the hepatitis B test in all cases of viral hepatitis, on the grounds that the ‘correct identification of the causative virus is important, as this may affect choice of prophylactic treatment of patients, contacts, or “at risk” workers’. As he observed, ‘before the present tests were available, these [cases] would have been incorrectly notified as infectious hepatitis, because most of the accepted criteria for classification as serum hepatitis would have been excluded’.<sup>109</sup>

In its 1979 annual report, the Health Department estimated the overall hepatitis B carrier rate in New Zealand to be 0.2 per cent, even though it was ‘higher in some ethnic and cultural groups’.<sup>110</sup> Nevertheless, despite these differences, the Department did not consider hepatitis B an important public health concern; while it noted that ‘hepatitis [B] is slowly increasing’, it added that ‘the number of cases reported is not high’. Mention was made of the ‘ever present’ risks to ‘those who get tattooed [and to] drug addicts using syringes’, but the Department’s main priority was the protection of people working in the health sector. Laboratory workers, in particular, merited special mention ‘because the infection is blood borne [and] laboratory workers who handle human blood samples are exposed to the risk of infection and must take special care’.<sup>111</sup>

## **Conclusion**

In the early 1970s, the focus of hepatitis B policy shifted from the protection of the blood supply to the prevention of hepatitis B virus infection among health care workers. The

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<sup>109</sup> A. Milne, ‘Letter to the Editor: Investigation of hepatitis’, *NZMJ*, 76, 27 April 1977, pp.347-8.

<sup>110</sup> *AJHR*, 1979, E-10, p.31.

<sup>111</sup> *ibid.*

sudden death of a young laboratory trainee prompted this transition in New Zealand; however, changes in policy and practice were already evident in the UK, where official responses were conditioned by the dialysis unit outbreaks, and in the US, where hepatitis B prevalence studies had confirmed health care workers as a 'high risk' group. While there was a variable uptake of Health Department policies intended to protect health care workers from exposure to hepatitis B virus infection, from the early 1970s a marked change occurred in the medical perception of the risks involved in routine health care.

The potential threat posed by hepatitis B infected health care workers to patients was recognised by the early 1970s; nevertheless, the risks of transmitting infection were regarded as 'rare'. Through their influence in the international research community, US researchers took the lead in developing international guidelines which emphasised the 'greater risks' posed by patients to health care workers.<sup>112</sup> This approach, which was widely endorsed by health professionals, also found favour among policy makers. In New Zealand, where the EAC set an early precedent against the routine screening of health care workers, the stance promoted by US researchers was readily accepted. By the late 1970s, there was widespread consensus that only those workers implicated in a cross infection should be excluded from providing direct patient care.

International influences were also evident in the approach taken to compensation for occupationally-acquired hepatitis B virus infection. With increased awareness of their 'at risk' status, New Zealand health care workers looked to the example set by laboratory workers in the UK in demanding compensation for work-related hepatitis B virus infections. By providing compensation under narrowly prescribed conditions, the ACC took an approach similar to that adopted by the UK health authorities.

During the 1970s, epidemiological surveys revealed the worldwide distribution of hepatitis B, and the high prevalence of the disease in 'third world' countries. Despite data suggesting a marked ethnic differential in the prevalence of hepatitis B in New Zealand,

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<sup>112</sup> WHO, *Advances in Viral Hepatitis: Report of the WHO Expert Committee on Viral Hepatitis: Technical Report Series No. 602*, p.45.

the Health Department assumed that local prevalence patterns would closely resemble those of the US and the UK. Within New Zealand, research was directed primarily at 'high risk' adults, and doctors made little use of the hepatitis B test as a diagnostic aid. As a result, at the end of the decade, health care workers remained the central focus of policy concern.



## CHAPTER FOUR

### PRESSURE TO PROVIDE CHILDHOOD HEPATITIS B IMMUNISATION

1980–1985

In the early 1980s, Alexander Milne, the Charge Laboratory Technologist at Whakatane Hospital, challenged orthodox beliefs on the epidemiology of hepatitis B in New Zealand. In the late 1970s, Milne's studies into the largely rural population of the Eastern Bay of Plenty had revealed an unexpectedly high prevalence of hepatitis B virus infection, particularly among Maori children. Armed with these findings, Milne questioned medical assumptions and proposed new policy responses. When the first hepatitis B vaccine was registered in New Zealand in late 1982, Milne and his medical collaborator, Dr Christopher Moyes, argued that immunisation policy should focus on children rather than adults, and that Maori children should be among the first to be protected against hepatitis B virus infection.

The Health Department had long supported immunisation as a key strategy for the control of vaccine-preventable diseases, yet it was reluctant to consider this approach for hepatitis B.<sup>1</sup> Not only did the high cost of the hepatitis B vaccine present a significant barrier to the widespread use of the vaccine, but other Western countries had prioritised the protection of health care workers, and 'at risk' adult groups. While health officials grudgingly acknowledged the need to protect the babies of hepatitis B carrier mothers, they did not support proposals for a targeted childhood immunisation programme.

During the early 1980s, Acquired Immune Deficiency Syndrome (AIDS) gained increasing attention as an international health issue. When the Fourth Labour

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<sup>1</sup> D. A. Dow, O. Mansoor, 'New Zealand immunisation schedule history', NZMJ, 109, 14 June 1996, pp.209-12. In 1980, the childhood immunisation schedule included diphtheria, tetanus, pertussis, polio, measles and rubella.

Government came to power in mid-1984, senior figures within the Health Department advised the new Minister of Health, Dr Michael Bassett, that New Zealand faced a potential AIDS crisis, while hepatitis B was a relatively minor issue on the health policy agenda.<sup>2</sup> As a consequence, Bassett did not anticipate the increasing community interest in hepatitis B prevention, or the public furore that followed his criticism of the locally funded hepatitis B initiatives led by Milne in the Eastern Bay of Plenty.

This chapter will discuss the period from 1980 to 1985, when hepatitis B evolved from a policy 'sleeper' to a politically charged issue that engaged the attention of the Health Minister and the Health Department, Maori organisations, the media, and the general public. As background to the events that took place in the early 1980s, it will begin by considering Milne's suspicions that hepatitis B was endemic in his local region, and the reluctance of doctors and senior health officials to respond to his concerns. It will then examine the issues that faced policy makers prior to the registration of the hepatitis B vaccine, and assess the influence of local prevalence studies. The Health Department's cautious approach to formulating an immunisation policy will be considered in the context of international policy recommendations, pre-existing perceptions of the disease, and the high cost of the hepatitis B vaccine. Lastly, the chapter will discuss the events that led to the appointment of a prominent Maori researcher and physician, Dr Eru Pomare, as an independent investigator of the Eastern Bay of Plenty hepatitis B immunisation programme, and his report to the Minister of Health in late 1985.

### **Alexander Milne**

Alexander (Sandy) Milne emerged as a central figure in hepatitis B research in New Zealand in the early 1980s. Even though Milne's prevalence studies in the Eastern Bay of Plenty in the late 1970s had revealed that hepatitis B was surprisingly common in local communities, he had difficulties convincing doctors that he had uncovered a serious

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<sup>2</sup> See for example, P. Parkinson, T. Hughes, 'The gay community and the response to AIDS in New Zealand', *NZMJ*, 100, 11 February 1987, pp.77-9; E. Plumridge, J. Chetwynd, 'AIDS policy response in New Zealand: consensus in crisis', *Healthcare Analysis*, 2, 1994, pp.287-95.



public health problem, and that children were among those most frequently infected by the disease.

Born in Scotland, Milne completed his laboratory training in Aberdeen and Edinburgh, before emigrating to New Zealand in the mid-1960s. Acute viral hepatitis was uncommon in Scotland, so that when he joined the Whakatane Hospital laboratory in 1967, Milne was surprised at the frequent cases of jaundice among local children.<sup>3</sup> In the early 1970s, as Chapter Three discussed, outbreaks of hepatitis A were a frequent occurrence in New Zealand communities, and doctors assumed that these cases were a result of poor hygiene or contaminated water supplies. When commercial hepatitis B testing kits were introduced to the laboratory in September 1976, 'out of interest', Milne began testing a range of blood specimens for the virus.<sup>4</sup>

Unlike larger towns and cities, Whakatane had no private pathology laboratory, so that the hospital laboratory processed most blood specimens from the Bay of Plenty Hospital Board area. From Milne's perspective, he had a unique overview of the local region: 'I ran the lab, [and] I saw the problem ... I wasn't supposed to be getting into research, but ... I got permission to do the testing and that was all that I needed'.<sup>5</sup> To begin with, he screened the blood of patients admitted to the hospital with jaundice, as well as blood samples from the patients of general practitioners diagnosed with viral hepatitis.<sup>6</sup> Later in 1976, after becoming aware of international studies on the transmission of the hepatitis B virus from carrier mothers to their babies, Milne initiated hepatitis B screening of the blood samples collected routinely from antenatal women.<sup>7</sup>

By early 1977, Milne began to suspect that hepatitis B virus infection was endemic in the Bay of Plenty. He approached Dr R. J. Flight, the Medical Officer of Health for the

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<sup>3</sup> C. D. Moyes, 'A National Programme to Control Hepatitis B in an Endemic Area', MD thesis, Cambridge University, 1990, p.35.

<sup>4</sup> A. Milne, interviewed by D. M. Jowitt, 29 August 2006.

<sup>5</sup> *ibid.*

<sup>6</sup> A. Milne, 'Viral hepatitis in the eastern Bay of Plenty', pp.87-91.

<sup>7</sup> A. J. Zuckerman, 'Maternal transmission of hepatitis', *Nature*, 249, 10 May 1974, pp.105-6; S. Mazzur, B. S. Blumberg, J. S. Freidlander, 'Silent maternal transmission of Australia antigen', *Nature*, 247, 1974, pp.41-3.

Rotorua health district, Dr Graeme Woodfield, Director of the Auckland Blood Transfusion Centre, and Dr William Hamilton, a virologist at the National Health Institute (NHI), Wellington, to discuss his findings.<sup>8</sup> However, as Vivien Edwards explained in her account of Milne's work, his concerns were 'rationalised and played down'. The doctors proposed more intensive laboratory testing, rather than widespread infection, as a reason for his findings. When interviewed for the *Whakatane Beacon*, Dr Brian Christmas, Deputy-Director of Public Health, attributed the high prevalence of hepatitis in the area to 'a seasonal increase ... at a local level'.<sup>9</sup> The doubts expressed by senior members of the medical profession rankled with Milne. In an interview with the *Dominion* in 1987, he recalled his frustration that there were 'all these little kiddies everywhere with yellow eyes – and no one wanted to know'.<sup>10</sup>

In his spare time, Milne began travelling throughout the Bay of Plenty region to discuss hepatitis B with laboratory staff, general practitioners (GPs) and the local press.<sup>11</sup> William Muraskin, who took a particular interest in Milne's role in raising awareness of the disease in New Zealand, wrote that 'during these early years ... Milne talked to everyone who would listen about the existence of the problem [and sent] strongly worded letters to the Department of Health about the need for action'.<sup>12</sup> At first, as Muraskin explained, Milne's 'superiors at the hospital were lukewarm about his activities. He could get test kits from the hospital, and was allowed to do his own work after hours, but they remained uncommitted' to his investigations.<sup>13</sup> Attitudes changed when Milne persisted in writing to the Health Department and the media about the 'problem' in the Eastern Bay of Plenty.<sup>14</sup> 'The Secretary of the Hospital Board informed [Milne] that his continued

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<sup>8</sup> Milne to Medical Superintendent-in-Chief, Whakatane Hospital, 23 March 1977; Milne to Flight, 12 October 1977, private papers, A. Milne.

<sup>9</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.14. Milne later acknowledged Hamilton's 'assistance and encouragement', and gave 'special thanks' to Woodfield and blood bank staff who tested his serum samples in the early 1980s using the more advanced methods available at the Auckland Blood Transfusion Centre. A. Milne, 'Viral hepatitis in the eastern Bay of Plenty', pp.87-91; A. Milne, C. D. Moyes, 'Hepatitis B carriage in children', pp.238-41.

<sup>10</sup> 'What makes Sandy run', *Dominion*, 30 August 1987, p.26.

<sup>11</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.14.

<sup>12</sup> W. Muraskin, 'Bucking the health establishment: Alexander Milne and the fight for a New Zealand hepatitis B immunization program', p.213.

<sup>13</sup> *ibid.*

<sup>14</sup> 'Editorial: Tell the people about hepatitis', *Whakatane Beacon*, 20 July 1977.

activity posed a direct danger to the [Whakatane] hospital's funding by the government'. Milne's response was to challenge the board; 'if they did not want [me] to speak out, they would have to put their demand in writing'.<sup>15</sup> Milne later described this as a gamble, 'I was either brave or foolish, and I think that I was both.' In the event, the board took no further action, and he continued to gather data and speak out as he saw fit.<sup>16</sup>

By mid-1979, Milne had tested the blood from 353 patients with viral hepatitis. A surprising number had hepatitis B virus infection; 152 (43 per cent) tested positive for the hepatitis B surface antigen, a serum marker of past or present infection. Moreover, almost half of the positive cases were children less than fifteen years of age, while a quarter were in the six to ten year old age group.<sup>17</sup> Milne had also tested over 2000 antenatal blood samples, of which 5.8 per cent of Maori women and 0.9 per cent of European women were chronic carriers of the virus. In a follow up study of 30 of the 72 babies born to carrier mothers, seven infants (23 per cent) developed the carrier state.<sup>18</sup> These findings confirmed his initial concerns over the high prevalence of hepatitis B in Eastern Bay of Plenty communities.

In 1979, Dr Christopher (Chris) Moyes, a UK paediatrician, joined the staff of Whakatane Hospital. Moyes expressed initial doubts over Milne's data, but by early 1980 he, too, was convinced that hepatitis B was an important health issue.<sup>19</sup> He and Milne developed a collaborative relationship that was central to their ongoing research. In many respects, they were opposites; Milne was obdurate and outspoken, whereas Moyes was more cautious and conservative in his views.<sup>20</sup> Despite their differences, the two men

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<sup>15</sup> W. Muraskin, 'Bucking the health establishment: Alexander Milne and the fight for a New Zealand hepatitis B immunization program', p.213.

<sup>16</sup> A. Milne, interviewed by D. M. Jowitt, 29 August 2006.

<sup>17</sup> A. Milne, 'Viral hepatitis in the eastern Bay of Plenty', pp.87-91.

<sup>18</sup> *ibid.*

<sup>19</sup> Moyes later wrote that 'Milne ... consulted me during the writing of the first paper on acute hepatitis in 1980, and since that time we have formed a consulting core team for all later work'. C. D. Moyes, 'A National Programme to Control Hepatitis B in an Endemic Area', p.4.

<sup>20</sup> Moyes described the differences between Milne and himself to William Muraskin: 'I am a doctor, who would have been inclined to sit back, wait till all the information is in and been sedate in print ... [whereas] Sandy has attributes that make it hard for doctors and bureaucrats to swallow'. W. Muraskin, 'Bucking the health establishment: Alexander Milne and the fight for a New Zealand hepatitis B immunization program', p.216.

became friends as well as co-investigators; Milne, a keen outdoorsman, introduced Moyes to trout fishing, and they planned many of their early prevalence studies whilst on expeditions to rivers in the local area.<sup>21</sup>

Moyes attributed Milne's difficulties in convincing senior doctors of the high prevalence of hepatitis B among Eastern Bay of Plenty children to a variety of issues. Not only was Moyes aware that Milne sometimes offended doctors by his lack of deference, but 'hepatitis B was assumed ... to be an uncommon disease', and Milne was 'only' a laboratory technologist, not a registered medical practitioner.<sup>22</sup> In an interview with Muraskin in 1992, Moyes maintained that issues of hierarchy, professional training and isolation worked against Milne, making it difficult for him to convey his concerns to medical colleagues. Moyes asserted that 'if the medical profession was going to learn something new and startling it should come from a medical specialist with credentials in a central hospital not from a technologist in a backwater place like Whakatane'.<sup>23</sup>

In New Zealand in the 1970s and early 1980s, medical experts held a central role in health policy making. High-ranking health officials Dr George Salmond and John Martin later wrote that during this period the medical elite exercised considerable control at both the local and national level: 'Locally, the medical superintendent and senior clinicians were dominant ... Other health professionals, and the lay boards elected to govern hospitals, subordinated themselves to [their] opinion, even on non-medical matters'.<sup>24</sup> Nationally, within the central health bureaucracy, the majority of high ranking officials were required by legislation to be members of the medical profession.<sup>25</sup>

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<sup>21</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.16.

<sup>22</sup> W. Muraskin, 'Bucking the health establishment: Alexander Milne and the fight for a New Zealand hepatitis B immunization program', p.216; C. D. Moyes, 'A National Programme to Control Hepatitis B in an Endemic Area', p.34.

<sup>23</sup> W. Muraskin, 'Bucking the health establishment: Alexander Milne and the fight for a New Zealand hepatitis B immunization program', p.213.

<sup>24</sup> J. Martin and G. Salmond, 'Policy-making: The Messy Reality', in P. Davis and T. Ashton, *Health and Public Policy in New Zealand*, p.46.

<sup>25</sup> D. A. Dow, *Safeguarding the Public Health: A History of the New Zealand Department of Health*, pp.209-10. This did not change until 1986, when amendments were made to the 1956 Health Act 'so that the Director-General and his deputies need no longer be doctors'.

Dr Ronald (Ron) Lucas, an infectious diseases specialist and Chief of Medicine at Fairfield Hospital, Melbourne, met Milne at an Australasian Hepatitis Symposium in 1981 and became a long-standing supporter of his research.<sup>26</sup> Lucas, who had great admiration for Milne, later described him as ‘a really extraordinary fellow ... [who] decides what need to be done and ... just goes at it in a straight line. He won’t stand any deviation’.<sup>27</sup> Lucas believed that professional divisions were particularly marked in New Zealand, where ‘one of the early impressions [he] had was that if you weren’t a doctor, you were almost nobody’. In his view he gave Milne ‘a certain degree of respectability’ through his specialist qualifications and standing in the medical world.<sup>28</sup>

Dr Donald (Don) Matheson, later appointed Deputy Director-General of Public Health, was a house officer at Whakatane Hospital in the early 1980s.<sup>29</sup> While Matheson described Milne as ‘a very unusual character ... typical of people who are totally into one issue, sometimes unkindly called “single issue fanatics”’, he thought highly of Milne’s ‘unbelievable energy’ and his dogged efforts to promote wider awareness of the hepatitis B problem. Matheson, too, considered that Milne’s lowly position as a laboratory technologist, the narrow geographical scope of his studies, and the lack of concern over hepatitis B in other western countries made it difficult for him to gain the attention and respect of policy makers. As he observed, ‘there was no particular international crisis or awareness about hepatitis B ... it was something that was found by someone very junior in the system and it was local’.<sup>30</sup>

In the early 80s, Milne found limited support within the New Zealand medical profession. His ‘exceptionally blunt’ manner could be off putting, and senior health officials were

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<sup>26</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.8.

<sup>27</sup> C. R. Lucas, interviewed by D. M. Jowitt, 9 July 2007.

<sup>28</sup> *ibid.* When Ron Lucas died in August 2009, his close friend and colleague, Fairfield Hospital virologist Ian Gust, who was a founding member of the International Task Force on Hepatitis B Immunization, described him as a ‘pioneer in the fight against hepatitis and HIV, online, available at: <http://www.smh.com.au/national/obituaries/pioneer-in-fight-against-hepatitis-and-hiv-20090812-ei8i.html> (28 August 2009).

<sup>29</sup> Don Matheson was Deputy Director-General of Public Health from 1999 to 2007.

<sup>30</sup> D. Matheson, interviewed by D. M. Jowitt, 20 August 2008.

unmoved by his claims that he had uncovered a significant public health problem.<sup>31</sup> Nonetheless, Milne attracted a small group of medical allies who were convinced of the importance of his findings, and who were prepared to provide assistance with his ongoing research.

### **Hepatitis B research in New Zealand in the early 1980s**

In 1981, the first vaccine against hepatitis B, which had been in development for almost a decade, was approved for use in the US.<sup>32</sup> The likelihood that small amounts of hepatitis B vaccine would be available in New Zealand by late 1982 drew attention to the need for more extensive information on the epidemiology of the disease and for a coordinated research programme.

In the early 1980s, no hepatitis B research was being undertaken at a national level in New Zealand. This was not indicative of the research interests of senior government scientists; on the contrary, both Dr Yvonne Hermon and Dr William Hamilton, virologists at the NHI, were keen to establish a hepatitis laboratory capable of providing diagnostic and epidemiological services.<sup>33</sup> In late 1977 Hermon had attended the World Health Organization (WHO) Interregional Seminar on Viral Hepatitis in Kuala Lumpur, where participants identified the need for a hepatitis surveillance programme.<sup>34</sup> However, when the WHO approached the Health Department in early 1979 with the recommendation that the NHI be designated one of six national centres for hepatitis research, the Department declined on the grounds that it had no 'suitable accommodation'. In 1981, a change of location was seen as an opportunity to develop the appropriate facilities, and in early 1982, the Department made a 'fairly firm commitment'

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<sup>31</sup> W. Muraskin, 'Bucking the health establishment: Alexander Milne and the fight for a New Zealand hepatitis B immunization program', p.216.

<sup>32</sup> Hepatitis Foundation, 'Hepatitis B Vaccine History', online, nd, available at: [http://www.hepb.org/professionals/hepatitis\\_b\\_vaccine.htm](http://www.hepb.org/professionals/hepatitis_b_vaccine.htm) (5 June 2010).

<sup>33</sup> In September 1981, Hamilton provided R. K. Logan, the Director of the NHI, with a proposal for a Hepatitis Laboratory at the NHI, 'the need for which is taken for granted'. Hamilton to Logan, 'Hepatitis Diagnostic and Reference Centre', 16 September 1981, ABQU 632 W4451/1 1/2/2, ANZW.

<sup>34</sup> WHO, *Report of an Interregional Seminar on Viral Hepatitis, 28 November-1 December 1977, Kuala Lumpur, Malaysia*, ABQU 6783 W4451/1 1/2/2.

to WHO to set up a national reference centre within the Institute.<sup>35</sup> Even so, in correspondence with Dr Bruce Chapman, a senior lecturer in gastroenterology at the Christchurch School of Medicine, R. K. Logan, the Director of the NHI, ‘hesitate[d] to forecast the rate at which progress w[ould] be achieved’.<sup>36</sup>

Chapman, who had been on sabbatical leave in the US and UK, had written to Logan suggesting that it would be ‘prudent’ to establish a hepatitis reference centre at one of the university teaching hospitals, rather than at the NHI. His contact with leading overseas researchers had convinced him of the urgent need to develop a national hepatitis B research capability. In his correspondence with Logan, Chapman discussed the importance of a national testing facility for the hepatitis B e antigen, a serum marker for highly infectious hepatitis B carriers. He put the view that health care workers exposed to the blood of these carriers should receive two doses of hepatitis B immunoglobulin, while babies born to mothers positive for the hepatitis B e antigen should receive ‘monthly doses for six months’. More importantly, in Chapman’s opinion, a costly vaccine against hepatitis B was likely to be widely available in the near future, which would require a better understanding of the local epidemiology of the disease so as to develop a ‘rational’ immunisation policy.<sup>37</sup>

Hepatitis B studies that were taking place in the early 1980s were initiated at a local level by interested individuals. In 1981, in Auckland, Dr Graeme Woodfield and Dr Keitha Farmer, a paediatric infectious diseases specialist at National Women’s Hospital, Auckland, began research into the prevention of hepatitis B in the babies of carrier mothers. The New Zealand Medical Research Council (MRC) had provided funding for this project, in recognition of the need to encourage hepatitis studies by local

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<sup>35</sup> Health Department, Paper for Director-General’s Meeting, ‘Hepatitis Diagnostic and Reference Centre’, 18 January 1982, ABQU 632 W4451/1 1/2/2, ANZW.

<sup>36</sup> Logan to Chapman, 22 January 1982, ABQU 632 W4451/1 1/2/2, ANZW. Logan’s predictions were correct; while the NHI developed its hepatitis B testing capacity, it never became a WHO reference laboratory.

<sup>37</sup> Chapman to Logan, 17 November 1981, ABQU 632 W4451/1 1/2/2, ANZW.

investigators.<sup>38</sup> During the same year, Milne and Moyes began a prevalence survey among babies and young children in the Eastern Bay of Plenty region.<sup>39</sup>

Milne was keen to gain wider recognition of his research efforts, both to raise awareness of the serious nature of the hepatitis B problem in New Zealand and to influence the policy making process. In late 1980, he had approached the EAC to seek support for the prevalence survey. The Chairman, Professor Kenneth Newell, who had established the Department of Community Health at the Wellington School of Medicine after a distinguished international career in epidemiology, indicated his willingness to be involved in the study design.<sup>40</sup> During the early 1980s, Newell became a key collaborator in Milne and Moyes' research, a role that continued after he left New Zealand for an academic post in the UK in late 1983.<sup>41</sup>

In mid-1981, the Health Department asked the EAC to consider the introduction of the hepatitis B vaccine in New Zealand. The US manufacturers recommended the vaccine for known risk groups, primarily health care workers and renal dialysis patients, but they also denoted other people who had 'close interpersonal contact' with hepatitis B carriers, including military personnel and homosexual men, as priority groups for vaccination. While these groups were considered at special risk in the US, the EAC questioned whether the distribution of 'risk groups' might differ in New Zealand. To clarify local conditions, the committee recommended that the 'Department of Health consider how information can be collected to review this matter as soon as practically possible'.<sup>42</sup>

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<sup>38</sup> K. Farmer, 'Prevention of the Vertical Transmission of Hepatitis B Antigen', paper presented at the Hepatitis B in New Zealand Workshop held at Whakatane Hospital, 23-25 June 1982, Pathology Laboratory, Public Hospital, Whakatane, *Hepatitis B in New Zealand: Report of a Workshop held at Whakatane*, 1982, p.14; D. G. Woodfield, K. Farmer, T. Gunn, 'Letter to the Editor: Vertical transmission of hepatitis B', *NZMJ*, 97, 20 September 1984, p.660; K. Farmer, T. Gunn, D. G. Woodfield, 'Passive immunoprophylaxis of hepatitis B virus infections in newborn infants', *NZMJ*, 98, 9 October 1985, pp.851-3.

<sup>39</sup> A. Milne, C.D. Moyes, 'Hepatitis B carriage in children', pp.238-41.

<sup>40</sup> EAC minutes, 27 November 1980, ABQU 786 8, W3045/8 ANZW. Newell came to the Wellington School of Medicine after ten years heading a research unit at the WHO in Geneva; C. Salmond, *The First 25 Years of the Department of Public Health (formerly Department of Community Health) at the Wellington School of Medicine and Health Sciences*, Wellington, 2004.

<sup>41</sup> C. D. Moyes, 'A National Programme to Control Hepatitis B in an Endemic Area', p.4.

<sup>42</sup> EAC minutes, 11 June 1981, ABQU 786 8, W3045/8, ANZW.



The Health Department's initial response to this advice was to remind doctors of their statutory obligation to notify viral hepatitis cases, and of the importance of differentiating those with hepatitis A from those infected with the hepatitis B virus.<sup>43</sup> The Department had been aware since the mid-1970s that the notification of hepatitis cases differed markedly between health districts, but, as Chapter Three discussed, it did little to improve the standard of reporting. With the introduction of a vaccine, however, health officials recognised that notification data would have greater significance. In a circular letter to medical practitioners early in 1982, the Department urged doctors to test for hepatitis B, on the grounds that 'the use of the vaccine will be restricted to those at high risk ... Epidemiological information will be necessary to decide which are the high risk groups in the New Zealand context'.<sup>44</sup>

By the end of 1981, neither the Health Department nor the EAC had access to accurate epidemiological data on which to base recommendations for a national immunisation policy. While the MRC actively encouraged local research, the Health Department remained ambivalent about developing national facilities for hepatitis research or providing incentives for a more expansive research programme. Its reluctance to do so reflected the low priority given to hepatitis B as a public health problem, and the prevailing medical belief that the disease was largely confined to health care settings.

### **The 1982 Whakatane workshop**

In early 1982, Alexander Milne submitted a joint proposal with the Health Department to the MRC for funding for a hepatitis B workshop for senior health professionals. The three-day workshop, held in Whakatane in June 1982, brought policy makers together with key figures in national and international hepatitis B research. The workshop was a major coup for Milne, who took the opportunity to highlight his research in the Eastern Bay of Plenty, and to encourage debate on the shape of future immunisation policy.

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<sup>43</sup> Viral hepatitis is difficult to distinguish on clinical grounds alone; laboratory testing is required to confirm a diagnosis.

<sup>44</sup> Department of Health, Circular Letter to Medical Practitioners, PH 1/82, January 1982, ABQU 632 W4451/1 1/2/2, ANZW.

Representatives from the Health Department, the MRC, the EAC, and the Transfusion Advisory Committee attended the Whakatane workshop, along with local hepatitis researchers and a sprinkling of senior medical specialists from around the North Island. Milne had also invited leading international figures: Abbott Laboratories, which produced hepatitis B test-kits, provided financial assistance to bring renowned husband-and-wife researchers Dr R. Palmer Beasley and Dr Lu Yu Hwang from Taiwan, while Merck, Sharpe and Dohme, the US-based pharmaceutical company whose hepatitis B vaccine was awaiting New Zealand registration, contributed towards the costs of bringing Ron Lucas from Melbourne.<sup>45</sup>

The Whakatane workshop was officially a shared venture between Milne and the Health Department, but Milne took responsibility for its location. In a letter inviting senior paediatric colleagues to the workshop in March 1982, Moyes acknowledged that Whakatane was an ‘unlikely venue’. He attributed the site of the workshop to the ‘considerable interest’ shown in hepatitis B by ‘our Charge Technologist Alexander Milne, who has produced some first class epidemiological information on the problem locally’.<sup>46</sup> As Milne had no doubt hoped, the workshop proved to be a highly effective forum for discussion and debate. Participants considered a wide range of topics, with much attention being given to the longterm complications of hepatitis B carriage, and the opportunities for hepatitis B prevention offered by the new vaccine. While some presenters focused on groups long considered to be at high risk of exposure to the hepatitis B virus, such as laboratory workers and hospital staff, others placed greater emphasis on infants and young children as at-risk groups.

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<sup>45</sup> Pathology Laboratory, Public Hospital, Whakatane, *Hepatitis B in New Zealand: Report of a Workshop held at Whakatane*, p.31. Beasley, a US infectious diseases physician and epidemiologist, was a member of the University of Washington Medical Research Unit in Taipei, Taiwan, from 1972 to 1986. University of Texas School of Public Health, 35<sup>th</sup> Anniversary Report, 2004, ‘Public Health Pioneer’, online, available at: <http://www.sph.uth.tmc.edu/brochure/beasley.htm> (2 June 2010).

<sup>46</sup> In his letter, Moyes indicated that important new issues had emerged, ‘including the use if any of the vaccine, and the extent to which we can affect the hepatitis pool by eliminating vertical transmission [from carrier mother to baby]’. Moyes to Holdaway, 9 March 1982, ‘Infectious Diseases and Immunisation Subcommittee; Prevention of hepatitis B in the community’, 9 March 1982, ABQU 632 W4415 50 29/19 53455, ANZW.

The keynote speakers, Beasley and Hwang, presented four papers on perinatal transmission of the hepatitis B virus, in which they stressed the importance of preventing infection among the babies of carrier mothers. Beasley and Hwang believed that so-called ‘vertical’ transmission was responsible for 40 per cent of the adult hepatitis B carriers in Asia, and that infection in infancy had a particularly ‘potent’ effect on the development of cirrhosis and liver cancer in adult carriers.<sup>47</sup> Their acclaimed study of over 22,000 civil servants in Taiwan, published in the *Lancet* in September 1981, confirmed that the risk of developing liver cancer was more than 200 times higher among lifelong hepatitis B carriers.<sup>48</sup>

Beasley and Hwang described hepatitis B immunoglobulin, a plasma product derived from blood donors who have recovered from hepatitis B infection, as ‘the only known way’ of preventing vertical transmission. Nevertheless, they suggested that a course of the new hepatitis B vaccine would provide additional protection for babies at risk of infection. At NZ\$150 per adult and NZ\$75 per child, however, they conceded that its high cost and limited supply might act as deterrents to its widespread use, and that financial considerations were likely to lead to restricted vaccination policies.<sup>49</sup>

While Milne acknowledged the importance of vertical transmission in Taiwan, he suggested that in New Zealand communities, child-to-child transmission might be more important in the spread of hepatitis B. From a survey conducted in 1981 and early 1982, he and Moyes had concluded that ‘a pool of young chronic carriers ... concentrated amongst the Maori population’, was responsible for the majority of infections among school-aged children.<sup>50</sup> Milne presented the results of this study, in which he and Moyes had tested 857 children and 157 infants in three local communities, as well as the mothers and family members of 46 children identified as hepatitis B carriers. They found that

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<sup>47</sup> Pathology Laboratory, Public Hospital, Whakatane, *Hepatitis B in New Zealand: Report of a Workshop held at Whakatane*, p.31.

<sup>48</sup> R. P. Beasley, L. Y. Hwang, C. Lin, C. Chien, ‘Hepatocellular carcinoma and hepatitis B virus: a prospective study of 22,707 men in Taiwan’; C. D. Moyes, ‘A National Programme to Control Hepatitis B in an Endemic Area’, p.27.

<sup>49</sup> Pathology Laboratory, Public Hospital, Whakatane, *Hepatitis B in New Zealand: Report of a Workshop held at Whakatane*, p.31.

<sup>50</sup> C. D. Moyes, ‘A National Programme to Control Hepatitis B in an Endemic Area’, p.44.

Maori children were at significantly higher risk of developing chronic hepatitis B virus infection; 12 per cent were hepatitis B carriers compared with 2.6 per cent of the European children.<sup>51</sup> Moreover, there was a marked increase in the prevalence of chronic infection among Maori children after school entry; 4.5 per cent of preschoolers were carriers compared with 20.5 per cent of five to nine year olds.

Milne and Moyes believed that these findings provided convincing evidence of the need to protect all children in the Eastern Bay of Plenty, not just the babies of carrier mothers, from the hepatitis B virus.<sup>52</sup> While Milne's paper stimulated debate over the most appropriate use of the hepatitis B vaccine in New Zealand, however, the overseas data proved more persuasive than the local findings. Participants discussed an ethnically or geographically targeted childhood immunisation programme, but they reached no definite conclusion. Instead, they recommended that the babies of highly infectious carrier mothers should be the first to receive the expensive vaccine once it became available.<sup>53</sup>

At its September 1982 meeting, the EAC discussed the recommendations resulting from the Whakatane workshop.<sup>54</sup> For the most part, the views expressed by EAC members reflected established assumptions about the prevalence of hepatitis B in New Zealand. Dr Max Collins, Director of the Public Health Division and a participant of the workshop, reported that it 'did not come to any conclusions about the Whakatane situation except to comment that the problem was both one of vertical transmission and subsequent infection'. Dr Selwyn Lang, a microbiologist at Middlemore Hospital, Auckland, and Dr Joan Faoagali, a microbiologist at Christchurch Hospital, both pointed to a 'distinct decline' in hospital admissions for hepatitis B from the late 1970s as an indication that the disease was of less concern than it had been earlier in the decade. Dr Francis de Hamel, a Dunedin public health physician, even queried 'whether the situation was

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<sup>51</sup> A. Milne, C. D. Moyes, 'Hepatitis B carriage in children', pp.238-41.

<sup>52</sup> C. D. Moyes, 'A National Programme to Control Hepatitis B in an Endemic Area', p.44.

<sup>53</sup> Pathology Laboratory, Public Hospital, Whakatane, *Hepatitis B in New Zealand: Report of a Workshop held at Whakatane*, p.9.

<sup>54</sup> EAC minutes, 13 September 1982, ABQU 786 8, 50 29/19 53455, ANZW.

serious enough to consider the importation of vaccine at \$150 a course'.<sup>55</sup> Kenneth Newell, however, argued that 'a case could be made that hepatitis B was a major cause of infection and its effects ... needed greater description ... particularly as the possibility for prevention was becoming available'. In summing up, he added that 'it appeared that Hepatitis B, as an infection, could in fact be widespread in New Zealand' and that 'questions [about the prevalence of hepatitis B] had gained greater importance ... because of the advent of a potent vaccine'.<sup>56</sup> As Chairman of the EAC, Newell took the lead, and the committee worked its way through the recommendations of the Whakatane workshop in detail.<sup>57</sup>

While the EAC gave its strong support to the use of hepatitis B vaccine to protect the babies of carrier mothers, there was general agreement that further prevalence studies were 'urgently' needed before it could give definitive advice on a broader immunisation policy. To progress research more rapidly, the committee recommended that its comments be forwarded to the MRC for 'urgent' consideration at its next meeting. Finally, to ensure the Whakatane workshop report reached a wider medical audience, the EAC proposed that it should be circulated to communicable disease specialists, medical laboratories, universities, medical officers of health, the Colleges of General Practice and Community Medicine, and to hospital infection control committees.<sup>58</sup>

While the Whakatane workshop raised the profile of hepatitis B as a public health issue and put Milne on the map as a hepatitis researcher, there was a mixed response to his findings.<sup>59</sup> Most members of the EAC were unconvinced that hepatitis B virus infection posed a widespread public health problem in New Zealand. Nevertheless, Newell gained unanimous support for further research to provide reliable data on which to base policy

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<sup>55</sup> *ibid.*

<sup>56</sup> *ibid.*

<sup>57</sup> *ibid.* The recommendations made by the Whakatane workshop participants ranged from improved notification procedures for hepatitis B to the development of a national liver cancer register.

<sup>58</sup> *ibid.*

<sup>59</sup> Don Matheson considered that Milne 'was largely ignored [by the medical establishment] until he held [the Whakatane workshop] and ... important people from overseas came along. No one in New Zealand took him very seriously before the [workshop], from what I could see'. D. Matheson, interviewed by D. M. Jowitt, 20 August 2008.

recommendations, and the EAC was in agreement that, at the very least, the new vaccine should be used to prevent infection in the babies of carrier mothers.

### **The Kawerau study 1983–1984**

In late 1982, on the advice of the EAC, the Health Department asked the MRC to coordinate hepatitis B research in New Zealand. Dr James (Jim) Hodge, Director of the MRC, approached Kenneth Newell to provide the epidemiological expertise and leadership for a hepatitis B research programme.<sup>60</sup> Newell was not only well qualified for the role, he was clearly keen to facilitate further prevalence studies.

Among the first projects to come to Newell's attention was a proposal for a total population study of the Bay of Plenty town of Kawerau.<sup>61</sup> In November 1982, Alexander Milne contacted Newell to review a study which 'aimed to define the patterns of hepatitis B virus infection ... in an entire community in order to decide which groups should receive priority for vaccination'.<sup>62</sup> A month later, Newell travelled to Whakatane to meet with Milne, Chris Moyes, and Dr Geoffrey (Geoff) Allwood, the pathologist at Whakatane Hospital. In his subsequent report to the MRC, Newell explained that Kawerau was a 'multi-racial town (approximately 30 per cent Maori) [with]...historical connections to Whakatane and [which] could be cooperative' towards a research study. He was in favour of the total population study which would be 'quite big ... and expensive' but which would 'help to clarify some of the Maori-Non Maori differences [in hepatitis B prevalence], identify carriers ... and describe age distributions'.<sup>63</sup>

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<sup>60</sup> Hodge was among the 33 participants at the Whakatane workshop. Hodge to Newell, 1 December 1982, YCBN 5990 17b part 1, ANZA.

<sup>61</sup> K. W. Newell, 'Report of a visit to Bay of Plenty Hospital Board, Whakatane, relating to hepatitis B research', 12-14 December 1982, YCBN 5990 17b part 1 of 3, ANZA.

<sup>62</sup> C. D. Moyes, 'A National Programme to Control Hepatitis B in an Endemic Area', p.46.

<sup>63</sup> K. W. Newell, 'Report of a visit to Bay of Plenty Hospital Board, Whakatane, relating to hepatitis B Research', 12-14 December 1982, YCBN 5990 17b part 1 of 3.

In early 1983, Newell called a meeting of ‘some investigators of hepatitis B’. Despite his lack of medical training, Milne was among the five researchers invited to attend.<sup>64</sup>

Newell was a masterful chair; while the group expressed differing views on the priorities for future research, he gained general agreement that there was a definite need for a hepatitis B task force ‘to give impetus to research ... to respond to the Dept. of Health as they move towards difficult policy decisions, and as a possible first step towards the establishment of a [national] Viral Hepatitis Research Centre’.<sup>65</sup>

Newell left for a new academic post in the UK eight months later, in October 1983, a move which Dr George Salmond, the Deputy Director-General of Health, described as putting ‘the future of the hepatitis B task force in question’.<sup>66</sup> Subsequently, at the November 1983 meeting of the MRC, Salmond argued that an ongoing programme of hepatitis B research should be given high priority by the Health Department and that the MRC should continue to actively encourage and support work in ‘this important area’. Moreover, Salmond contended that ‘the need to provide some national oversight is made the more urgent by the likelihood that the MRC will fund a \$50,000 project in [Kawerau] directed by Mr Milne’.<sup>67</sup> In the event, the grant was more generous than Salmond had anticipated; in December 1983 the *Whakatane Beacon* reported that the MRC had awarded ‘the Whakatane group’ \$71,000 to undertake the 12 month prevalence survey.<sup>68</sup>

Kawerau lies 27 kilometres south-west of Whakatane, towards the central North Island town of Rotorua. In 1983, it had approximately 8,500 residents, of which two-thirds were European. Among the children, the population was evenly split between Maori and

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<sup>64</sup> The others, all medical specialists, were: Dr Graeme Woodfield, Dr Yvonne Hermon, Dr Joan Faoagali, both members of the EAC, and Dr Frank Austin, a virologist from the MRC Virus Research Unit in Dunedin.

<sup>65</sup> Minutes of an MRC Meeting of Some Investigators of Hepatitis B, 1 February 1983, YCBN 5990 17b part 1 of 3, ANZA.

<sup>66</sup> Salmond to DGH, Christmas and Martin, 14 November 1983, YCBN 5990 17b part 2 of 3, ANZA.

<sup>67</sup> *ibid.*

<sup>68</sup> ‘\$70,000 grant for huge hepatitis study’, *Whakatane Beacon*, 16 December 1983.

Pakeha.<sup>69</sup> In some ways, Kawerau was characteristic of Bay of Plenty townships, but in others, it was unique. Moyes later wrote that

The town of Kawerau was chosen for its suitable size and geographic convenience, an appropriate mix of European and Maori ... [and] a strong community spirit ... Kawerau [was], however, not typical of New Zealand towns in being a new creation in 1953 to service a newsprint, paper and lumber industry. Nearly all the workforce [was] employed directly or indirectly by two large industrial plants processing [pine trees] from the giant man-planted forests on the volcanic plateau further inland.<sup>70</sup>

To gain the support of the Kawerau community, Milne, Moyes and Allwood took a strategic approach to ensuring the whole township was involved in the survey.<sup>71</sup> After meeting with local doctors and community leaders, they organised a series of public meetings and a promotion on the local marae, then discussed the project with staff and pupils at local schools. Milne sent press statements to the *Kawerau Gazette*, and he and Moyes took part in radio interviews and talkback shows. As a result of their intensive public relations campaign, the majority of Kawerau residents became enthusiastic supporters of the study.<sup>72</sup> In January 1984, the *Whakatane Beacon* reported that the Tasman Pulp and Paper Company had offered the time of two nurses to take blood samples from their 2,500 employees, more than a quarter of the total number of people to be tested.<sup>73</sup> When the survey was completed, 98 per cent of the children had come forward, with 93 per cent of residents overall participating in the study.<sup>74</sup>

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<sup>69</sup> 'At the 1981 census, three years before this study, the population was 8,568, comprising 61% European, 35% Maori (or part Maori), and 2% Pacific Islanders.' C.D. Moyes, 'A National Programme to Control Hepatitis B in an Endemic Area', p.46.

<sup>70</sup> *ibid.*

<sup>71</sup> Not all Kawerau residents were in favour of the study. Milne later recalled that at local meetings, some people told him that he was 'giving the town a bad name' and that 'hepatitis B hadn't been as problem till I brought it'. A. Milne, interviewed by D. M. Jowitt, 29 August 2006.

<sup>72</sup> 'Kawerau rush to have blood test', *Whakatane Beacon*, 29 February 1984; 'Amazing response to hepatitis survey', *Whakatane Beacon*, 9 March 1984.

<sup>73</sup> 'Tasman's major offer of aid in hepatitis study' *Whakatane Beacon*, 25 January 1984.

<sup>74</sup> Babies under six months of age were not tested, otherwise all residents of Kawerau were encouraged to participate in the survey. A. Milne, G. K. Allwood, C. D. Moyes, N. E. Pearce, C. R. Lucas, 'Prevalence of hepatitis B infections in a multiracial New Zealand community', pp.530-1.



By March 1984, preliminary results indicated that hepatitis B was endemic in Kawerau: 33 per cent of Europeans and 55 per cent of non-Europeans (mainly Maori) had markers of past or present infection. Overall, 519 people (6.6 per cent of the total population surveyed) were chronic carriers of the disease. Most new infections appeared to occur among children, especially in the primary school years: ‘At the age of four years, approximately 6 per cent of Europeans and 17 per cent of non-Europeans [had] evidence of [past or present] infection, but by the age of 14 years these rates had risen to 57 per cent and 71 per cent respectively’. Non-European children were also at greater risk of becoming chronic carriers of the virus.<sup>75</sup>

The Kawerau study, which produced clear evidence of endemic hepatitis B virus infection among both Maori and European children, was an important landmark in New Zealand hepatitis B research. Unlike Taiwan, where vertical transmission was known to be a major problem, or other Western countries, where hepatitis B virus infection was concentrated within adult populations, the Kawerau study suggested that in New Zealand, child-to-child transmission was the primary mode of spread.<sup>76</sup>

While the startling rates of infection revealed by the Kawerau study attracted widespread attention in New Zealand and overseas, they appeared to represent an extreme in local prevalence patterns. Surveys conducted by Milne and Moyes among children in other parts of the Bay of Plenty produced more moderate results, suggesting that Milne and Moyes happened on a location of particularly high hepatitis B prevalence. Dr James (Jim) Faed, the Regional Transfusion Officer for Otago, and a member of the Transfusion Advisory Committee, for example, considered that Milne was ‘dead lucky’ to have stumbled on a ‘microcosm in which hepatitis B spread more readily’, as ‘this helped strengthen the statistical case for vaccination’.<sup>77</sup> Nonetheless, the results of the Kawerau study were widely publicised as evidence of the serious nature of the hepatitis B problem

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<sup>75</sup> *ibid.*

<sup>76</sup> C.D. Moyes, ‘A National Programme to Control Hepatitis B in an Endemic Area’, p.53.

<sup>77</sup> J. M. Faed, interviewed by Deborah Jowitt, 8 November, 2006.

in New Zealand, and the survey would prove influential in raising public awareness of the unexpectedly high prevalence of hepatitis B in New Zealand and in policy debates.

### **EAC advice on immunisation and Health Department responses**

In late 1983, the EAC developed definitive recommendations for a targeted hepatitis B immunisation policy, however, the Health Department proved reluctant to act. While the EAC was the official advisory body on vaccine matters, in the case of hepatitis B, WHO recommendations took precedence over local guidance.

In April 1983, the EAC made its initial recommendations to the Health Department on hepatitis B immunisation policy. The EAC based its advice on recently formulated Australian National Health and Medical Research Council (NHMRC) policy, and on a proposal submitted by Alexander Milne on his return from a hepatitis B meeting in Melbourne.<sup>78</sup> Like health authorities in other Western countries, the NHMRC regarded health care workers as the first priority for hepatitis B immunisation. Almost all other groups seen to be at substantial risk were adults: ‘patients requiring frequent exposure to blood or blood products ... staff and inmates of prisons, migrant hostels and hostels for drug addicts ... [and] promiscuous male homosexuals’. However, the NHMRC also advised that ‘information on the safety and efficacy of the hepatitis B vaccine for the babies of carrier mothers should be sought as a matter of urgency ... and the vaccine be approved for use in such infants as soon as possible’.<sup>79</sup>

In the early 1980s, even though policy makers focused on the protection of high risk adults, the babies of carrier mothers were widely recognised as an important ‘at risk’ group. Experts in hepatitis control, such as Professor Arie Zuckerman, a UK virologist and a member of the WHO Scientific Group on Viral Hepatitis, vigorously promoted this

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<sup>78</sup> NHMRC, ‘Hepatitis Vaccine – Priorities of Need: Interim Recommendation’ (undated); Milne to Lang, ‘Priorities for vaccination against hepatitis B’ (undated); YCBN 5990 17b part 1 of 3, ANZA.

<sup>79</sup> NHMRC, ‘Hepatitis Vaccine – Priorities of Need: Interim Recommendation’ (undated); NHMRC, ‘News Release: Hepatitis B Vaccine’, 20 April 1983, YCBN 5990 17b part 1 of 3, ANZA.

aspect of vaccine policy.<sup>80</sup> By early 1983, both the WHO and CDC advised that the babies of carrier mothers should be among the priority groups for hepatitis B immunisation to prevent ‘vertical’ transmission of the virus and the early development of the carrier state.<sup>81</sup>

Milne, whose own research had convinced him that the majority of local carriers had ‘acquired the virus from sibs [sic] or other contacts, seldom the mother’, produced an alternative proposal which he submitted to the EAC in early 1983. ‘High-risk worker groups ... coming into contact with the body fluids of Maoris will no doubt demand protection’, he began, ‘But I wish to make a plea that ... young children and babies should have first priority’. Milne’s list started with ‘all Polynesian children at birth’, followed by all susceptible pre-school Polynesian children, European preschoolers in close contact with Polynesian children, all ‘at-risk’ children, and finally a broad catchall of ‘others as agreed’. Four prominent international hepatitis B researchers had endorsed his submission.<sup>82</sup>

While EAC members generally concurred with Milne’s emphasis on protecting children, they considered that other childhood groups were at greater risk of hepatitis B virus infection. After discussion, the EAC developed its own priority ranking for consideration by the Health Department: the children of highly infectious carrier mothers, haemophiliac children, institutionalised children with intellectual impairment, and finally, ‘all Polynesian children at birth ... as per Mr Milne’s list’.<sup>83</sup>

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<sup>80</sup> A. J. Zuckerman, ‘Maternal transmission of hepatitis’, *Nature*, 249, 10 May 1974, pp.105-6; A. J. Zuckerman, ‘Priorities for immunisation against hepatitis B’, *British Medical Journal*, 284, 6 March 1982, pp.686-8.

<sup>81</sup> F. Deinhardt, I. D. Gust, ‘Viral hepatitis’, *Bulletin of the World Health Organization*, 60, 5, 1982, pp.661-91; Recommendation of the Immunization Practices Advisory Committee (ACIP), ‘Inactivated hepatitis B virus vaccine’, *MMWR*, 31, 25 June 1982, pp.317-28.

<sup>82</sup> The signatories included renowned US researchers R. Palmer Beasley and Harvey Alter, as well as members of the Australasian Society for Infectious Diseases. A. Milne, ‘Priorities for vaccination against hepatitis B’, a paper prepared for the Epidemiology Advisory Committee (undated), EAC minutes, 7 April 1983, AAFB 786 W3045/8, ANZW.

<sup>83</sup> EAC minutes, 7 April 1983, AAFB 786 W3045/8, ANZW.

The Health Department's initial reaction to the EAC recommendations was to reduce them by three-quarters. While the EAC played an important role in advising the Health Department on immunisation issues, the Department also looked to the WHO when making policy decisions. In her 2008 PhD thesis, Alison Day explained that from 1960 onwards, the EAC, as 'New Zealand's panel of experts, guided immunisation policy by making recommendations to the Health Department'. Nevertheless, she concluded that 'The WHO [also] exerted great influence over immunisation procedure and policy development in New Zealand with the Health Department committed to undertaking active roles in the WHO itself.'<sup>84</sup> Dr John Hiddlestone, Director-General of Health from 1973 to 1983, was 'Vice-President of the World Health Assembly in 1976, a member of the WHO Executive Board in 1980 and Chairman in 1982'.<sup>85</sup> In the case of hepatitis B, WHO endorsement of the babies of carrier mothers as a priority group for immunisation clearly shaped departmental responses.

In June 1983, the Health Department asked the EAC to consider four further policy options, centred on the babies of carrier mothers. The EAC gave its unanimous support to the immunisation of the babies of highly infectious hepatitis B carrier mothers with immunoglobulin and vaccine, and the immunisation of the close family contacts of identified carriers.<sup>86</sup> Mindful of the expense of the vaccine, the committee put aside the proposal that the babies of all carrier mothers be immunised 'at this time, on the grounds of cost'.<sup>87</sup>

The high cost of the hepatitis B vaccine was a major consideration for policy makers.<sup>88</sup> In the early 1980s, New Zealand, like other developed countries, faced difficulties funding the health sector, in which expenditure was increasing at 'rates substantially higher than

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<sup>84</sup> A. S. Day, 'Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920 – 1990', p.93.

<sup>85</sup> *ibid.*, p.200.

<sup>86</sup> The babies of highly infectious carrier mothers, i.e. hepatitis B e antigen positive mothers, were at high risk of being infected and developing the carrier state.

<sup>87</sup> EAC minutes, 23 June 1983, AAFB 786 W3045/8, ANZW.

<sup>88</sup> Vaccines against diphtheria, polio and measles, for example, cost less than a dollar a dose, whereas a three dose course of hepatitis B vaccine cost \$75 for children and \$150 for adults.

real economic growth'.<sup>89</sup> In the UK, Jennifer Stanton explained that the high cost of the vaccine, over £60 per adult course, was a major obstacle to the implementation of hepatitis B immunisation policies for health care workers.<sup>90</sup> Similarly, in the US, where a course of the vaccine was \$100, William Muraskin argued that the 'chief problem [preventing its widespread use] was its price'.<sup>91</sup>

In New Zealand, in mid-1982, Robert (later Sir Robert) Muldoon, the Prime Minister and Finance Minister of the National Government, had imposed a wage and price freeze to curb inflationary pressures on the New Zealand economy. While this policy did not preclude spending on politically important health issues, it did constrain Health Department activities. As Aussie Malcolm, Health Minister from 1981 to 1984 explained, 'there was not enough money to do everything one wanted [but] there were always other strategies available that freed misallocated money for more appropriate uses'.<sup>92</sup> With regard to hepatitis B, however, Malcolm saw no need to introduce an immunisation programme. From Malcolm's perspective, and presumably from that of his departmental advisers, the apparently limited extent of the problem did not warrant this step.<sup>93</sup>

Throughout 1983, despite repeated recommendations by the EAC members for the introduction of an immunisation policy targeting the babies of carrier mothers, the Health Department did not act.<sup>94</sup> Given the high cost of the vaccine, and the views of high-ranking health officials on the relative importance of hepatitis B as a public health issue, this was hardly surprising. Nevertheless, the apparent indifference to local data was also indicative of the caution and conservatism that characterised the health bureaucracy.

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<sup>89</sup> T. Ashton, 'The Influence of Economic Theory', in P. Davis and T. Ashton, *Health and Public Policy in New Zealand*, p.108.

<sup>90</sup> J. M. Stanton, 'What shapes vaccine policy? The case of hepatitis B in the UK', pp.427-46.

<sup>91</sup> W. Muraskin, 'Hepatitis B as a model (and anti-model) for AIDS', in V. Berridge and P. Strong, *AIDS and Contemporary History*, p.117; Recommendation of the Immunization Practices Advisory Committee (ACIP), 'Inactivated hepatitis B vaccine', pp.317-28.

<sup>92</sup> A. Malcolm, email communication, 3 February 2008.

<sup>93</sup> As Malcolm later reflected, '[I had] a respect for what [Milne] knew in his environment with his specialisation but I was not confident that the kids at Wadestown Primary School [in Wellington] were at risk from hepatitis B'. A. Malcolm, interviewed by Deborah Jowitt, 13 February 2008.

<sup>94</sup> See for example, the EAC minutes for 13 October 1983, in which the EAC 'expressed its concern that its recommendations on hepatitis B immunisation be given urgent consideration at a decision-making level in the Department'.

Alison Day concluded that the Department was generally very slow to adjust its views and that its responses to hepatitis B immunisation demonstrated this.<sup>95</sup> Others believed that the Health Department had an entrenched ‘wait and watch’ attitude to health issues. Neil Pearce, a Wellington biostatistician who participated in the Kawerau study, for instance, attributed departmental inaction on hepatitis B to ‘the natural inertia which it has had for decades so that whenever any controversy blows up, it is a storm in a teacup and the best thing to do is to just be calm and sensible and do nothing’.<sup>96</sup>

In late 1983, in what appeared to be another delaying tactic, the newly appointed Director-General of Health, Dr Ronald (Ron) Barker, asked the EAC to revise its priorities for hepatitis B immunisation. Following Kenneth Newell’s departure, Max Collins, Director of the Division of Public Health, had been appointed Chairman of the EAC, yet there appeared to be no signs of advocacy for hepatitis B immunisation from within the Department. In response to Barker’s request, the EAC provided a further list targeting the babies of carrier mothers and ‘at risk’ children.<sup>97</sup>

High-level resistance to formulating a hepatitis B policy was even more obvious in April 1984, when Collins reported to the EAC that although the Health Department had approved in principle a proposal for immunising newborn babies at risk, ‘there was still some work to be done ... before this became policy’. He explained that ‘The Director-General’s Group had expressed an interest in what was happening in other countries as it did not believe that New Zealand should be the first country to introduce a national Hepatitis B immunisation policy.’ According to Collins, the Director-General intended to discuss the issue on a forthcoming trip to Geneva, where he was to attend a WHO meeting.<sup>98</sup>

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<sup>95</sup> A. S. Day, ‘Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920 – 1990’, p.226.

<sup>96</sup> N. E. Pearce, interviewed by D. M. Jowitt, 9 November 2007.

<sup>97</sup> This list was as follows: ‘neonates born to infectious mothers ... children who are close contacts of individuals known to be infectious, haemophiliacs, and children attending certain preschool institutes and in residential institutes’. EAC minutes, 15 December 1983, AAFB 786 W3045/8, ANZW.

<sup>98</sup> EAC minutes, 5 April 1984, AAFB 786 W3045/8, ANZW.

At its April meeting, the EAC reviewed the results of a recent hepatitis B survey conducted by the NHI. In the late 1970s, NHI scientists had collected blood samples from almost 2000 children from around New Zealand for a poliomyelitis survey. This collection had been re-tested for markers of hepatitis B infection. In many respects, the results substantiated Milne's earlier findings: Maori children were twice as likely to have (past or present) hepatitis B virus infections as European children and were three times more likely to become chronic hepatitis B carriers. However, it also revealed a marked geographic differential in infection rates; the risk of contracting the disease among North Island children appeared to be three times greater than for children living in the South Island. These findings gave added impetus to the argument for the introduction of a childhood immunisation programme, particularly in North Island regions.<sup>99</sup>

As Chairman of the EAC, Collins appeared non-committal about the NHI survey. The minutes record his comments: 'because it was not a random sample ... the results were not precise enough to be quoted dogmatically [even though] they did give some idea of the prevalence of hepatitis B in the country at present'. When Collins tried to cut short a discussion on the most appropriate hepatitis B tests for screening antenatal women, however, the committee objected. It had been over 12 months since the EAC had first recommended a policy for the protection of the babies of carrier mothers. Despite the presence of three senior departmental representatives on the committee, no action had been taken.<sup>100</sup> A short statement captured the committee's mood: 'members expressed the wish that the Health Department expedite this matter'.<sup>101</sup>

Three months later, in July 1984, the EAC discussed the preliminary results of the Kawerau study, which provided a striking contrast to the hepatitis B prevalence rates

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<sup>99</sup> *ibid.*

<sup>100</sup> These were Dr R. Campbell Begg, Director of Health Promotion, Dr Max Collins, Director of the Division of Public Health, and Dr John Clements, Assistant Director of the Division of Disease Prevention.

<sup>101</sup> Departmental inaction did not prevent individual hospital boards from instituting their own protocols to protect newborn babies born to carrier mothers. In 1984, on the advice of their staff paediatricians, obstetricians and pathologists at both Northland Area Health Board and Waikato Hospital Board had decided to give the babies of all carrier mothers hepatitis B immunoglobulin at birth and to repeat the dose at six weeks of age if the mother proved to be a highly infectious carrier on further testing. Maxwell to Clements, 30 July 1984, YCBN 5990 17b part 2 of 3, ANZA; EAC minutes, 5 April 1984, AAFB 786 W3045/8, ANZW.

reported in the NHI survey. To clarify the situation, the committee recommended that there was ‘a real need for the Health Department to investigate ... what made Kawerau so different from the rest of the country’.<sup>102</sup> The likelihood of this happening was remote, however; in the three month interval between EAC meetings, the Department had made no advances in immunisation policy.<sup>103</sup>

This was to be the EAC’s last meeting. In mid-July 1984, the National Government went to the polls. The snap election delivered an unexpected victory for the Labour Party, which had been nine years in the opposition benches. Michael Bassett, the newly appointed Health Minister, had campaigned on a health manifesto that promised to foster ‘community involvement in the planning and provision of health services’ and encourage ‘further research into Maori health’.<sup>104</sup> In late 1984, as part of a wider review of ministerial advisory committees, he disbanded the EAC and appointed a new advisory body, the Communicable Disease Control Advisory Committee (CDCAC), to provide guidance on epidemiological matters. The CDCAC met for the first time in February 1985, but in the six month hiatus the Health Department made no further progress on policy making.<sup>105</sup>

From 1983 to 1984, therefore, despite persistent efforts by some members of the EAC, the Health Department failed to develop a hepatitis B immunisation policy. Health officials apparently rejected the notion that hepatitis B could be a significant public health problem affecting New Zealand communities, and the high cost of the hepatitis B vaccine acted as an additional deterrent to the introduction of an immunisation programme.

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<sup>102</sup> EAC minutes, 19 July 1984, AAFB 786 W3045/8, ANZW.

<sup>103</sup> In July 1984, Dr John Clements, Medical Secretary of the EAC, prepared a list of Circular Memoranda on hepatitis B issued since 1971. In the preamble he stated: ‘The Department of Health has not yet formulated a policy for the control of this disease’, and later, ‘the wider use of the vaccine is under consideration’. C.J. Clements, ‘Hepatitis B Infection Control: Policy of the Department of Health as at July 1984’, Notes prepared for the MRC Working Party on Viral Hepatitis, YCBN 5990 17b part 2 of 3, ANZA.

<sup>104</sup> New Zealand Labour Party, *1984 Policy Document: New Zealand Labour Party*, Wellington, 1984, pp.38-9.

<sup>105</sup> CDCAC minutes, 15 February 1985, Ministry of Health Archives, Wellington.



## Community-funded hepatitis B immunisation in Kawerau

While the 1984 Kawerau survey had revealed that hepatitis B was endemic among the local population, not all children had been affected, and Alexander Milne was determined to find a means of protecting those still susceptible to the virus. Milne's commitment and 'can-do' attitude appealed to local people, who were motivated by his enthusiasm for community-funded hepatitis B immunisation.

In mid-1984, Milne began to investigate a means of immunising Kawerau children yet to be infected by hepatitis B. Both his integrity and the children's well-being were at stake; as William Muraskin explained, 'Milne had promised the townspeople that after [the survey] was over their susceptible children would be vaccinated'.<sup>106</sup> Local timber unions had donated substantial sums towards an immunisation programme, but even so, their donations would not cover the costs of a full dose vaccine campaign.<sup>107</sup> Milne was aware of overseas trials using low-dose hepatitis B vaccine administered to adults by the intradermal route.<sup>108</sup> Discussions with Dr Paul Goldwater, an Auckland virologist, convinced him that the manufacturer's recommended dose of hepatitis B vaccine for children was not only expensive, it was unnecessarily high.<sup>109</sup> Milne contacted Professor Saul Krugman at the New York University School of Medicine, an acknowledged expert on hepatitis B vaccination in childhood, for advice. Krugman recommended a pilot study using 2 mcg, or one-fifth of the manufacturer's recommended dose of vaccine, before embarking on a full scale programme. He also offered to act as a co-investigator on the low dose vaccine trial.<sup>110</sup>

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<sup>106</sup> W. Muraskin, 'Bucking the health establishment: Alexander Milne and the fight for a New Zealand hepatitis B immunization program', p.215.

<sup>107</sup> 'Mystery gift of \$10,000 for vaccine', *Whakatane Beacon*, 15 February 1984; 'Donation source disclosed', *Kawerau Gazette*, 23 February 1984.

<sup>108</sup> Hepatitis B vaccine is given into the muscle of the upper arm or thigh. Intradermal administration, into the dermal layer of the skin, is not recommended as it is more painful, particularly in children, and the vaccine is less likely to be absorbed from this site.

<sup>109</sup> Paul Goldwater, Graeme Woodfield and colleagues later published a study that demonstrated the efficacy of intradermal hepatitis B immunisation among medical students. P. N. Goldwater, D. G. Woodfield, A. M. Ramirez, I. Steed, 'Intradermal, low dose, short course hepatitis B vaccination', *NZMJ*, 99, 24 September 1986, pp.703-5.

<sup>110</sup> Milne found Krugman an immediate source of support: 'I rang New York and said ... could you give me some advice. [Krugman] said tell me what the problem is. I said I'm in New Zealand, and in the indigenous population we have carrier rates up to 15 to 20 per cent, and he said what! You'll be vaccinating

Milne then turned to the people of Kawerau to gain their approval for a pilot study.<sup>111</sup> He proposed a low dose option instead of the full dose vaccine on the grounds that approximately \$60,000 to \$70,000 would be required if all susceptible children less than 10 years were to be protected by the standard dose of vaccine, but that community funds already in hand would almost cover the cost of a low dose vaccination campaign.<sup>112</sup> Milne had timely support for his proposal; Ron Lucas arrived in Whakatane in late June 1984.<sup>113</sup> Lucas was typically plain-spoken when interviewed by the local press: 'It would cost the Kawerau community a hell of a lot less ... it would work well, and the results ... would give valuable information not only for the rest of New Zealand but for the world'.<sup>114</sup> In early July 1984, Kawerau community representatives gave the go-ahead for the low dose vaccine trial.<sup>115</sup>

Milne sought further financial backing for the low dose programme by submitting an application for research funding to the newly-formed MRC Working Party on Viral Hepatitis. In May 1984, Dr Clifford (Cliff) Tasman-Jones, a leading Auckland gastroenterologist, had been appointed as 'Convenor and Chairman' of this committee, which the MRC envisaged as an expert medical group which would oversee research and provide technical advice.<sup>116</sup> The group declined Milne's application for funding, on the grounds of 'weaknesses in the study design'.<sup>117</sup> Milne was unimpressed by this response; to his co-workers in Whakatane he observed that 'a new "Expert Committee" consisting

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your children then won't you, and I said no, they're not even interested!' A. Milne, interviewed by D. M. Jowitt, 29 August 2006.

<sup>111</sup> Even though he supported its use, Chris Moyes 'was absent during the pilot study of low dose vaccine and its first extension to Kawerau children'. C. D. Moyes, *A National Programme to Control Hepatitis B in an Endemic Area*, p.4.

<sup>112</sup> 'Now Kawerau must decide', *Kawerau Gazette*, 26 June 1984.

<sup>113</sup> Lucas, who was en route to study Acquired Immune Deficiency Syndrome (AIDS) at the CDC headquarters in Atlanta, Georgia, planned to spend the first half of his sabbatical leave analysing the data from the Kawerau survey. C. R. Lucas, interviewed by D. M. Jowitt, 9 July 2007.

<sup>114</sup> 'Expert recommends low-dose option', *Kawerau Gazette*, 26 June 1984.

<sup>115</sup> 'Town to tackle child hepatitis', *Rotorua Post*, 17 July 1984.

<sup>116</sup> Anon., 'WHO viral hepatitis programme', *NZMJ*, 26 September 1984, p.652.

<sup>117</sup> Minutes of the MRC Working Party on Viral Hepatitis in New Zealand, 25 June 1984, YCBN 5990 17b part 2 of 3, ANZA.

solely of doctors, is in existence. It appears to meet for about two hours every month or two, to consider New Zealand's most serious viral disease'.<sup>118</sup>

To gain wider support for the immunisation campaign, Milne sought the assistance of the news media. A number of journalists, including Andrew Pirie, health reporter for the *Dominion*, gave the project regular coverage.<sup>119</sup> In early October 1984, the Health Minister, Michael Bassett, issued a press release in response to the growing public interest in hepatitis B, in which he claimed that the 'one of the major difficulties in dealing with the spread of hepatitis B has been the high cost of the vaccination'. The editor of the *Dominion* penned an immediate response, challenging Bassett to act on the hepatitis B problem:

Dr Bassett finds the high incidence of hepatitis B in some parts of New Zealand "most disturbing". So indeed will most New Zealanders ... Research is showing that the incidence in places like Kawerau ... can be 50 to 100 times higher than in London or Melbourne ... What is to be done? A vaccine is available ... Why, then, has the Department of Health not engaged in a nationwide programme similar to the anti-diphtheria, polio and whooping-cough campaigns. The excuse is cost. Dr Bassett says cost has been a block to any large-scale vaccination programme. Granted it is costly, but what price is to be put on the suffering of those experiencing the disease and the long-term consequences of its spread? ... We must get our priorities right ... the efficacy of the cheaper dose should be established beyond doubt soon. Dr Bassett ... must be ready ... to order an immediate campaign – whatever the cost.<sup>120</sup>

Milne, a long time Labour supporter, had expected that the change of government would bring a fresh perspective on hepatitis B immunisation. When he approached Bassett for a financial contribution towards the Kawerau programme, however, the Minister rejected his request. Bassett, whose senior advisers regarded hepatitis B as an issue best left on the

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<sup>118</sup> 'Whakatane Public Hospital Laboratory Hepatitis B Research Projects: Newsletter for Co-investigators and others', 28 August 1984, private papers, A. Milne.

<sup>119</sup> The *Dominion* was a widely read daily newspaper, published in Wellington, the capital city and seat of the New Zealand parliament. Pirie was responsible for a number of articles promoting childhood hepatitis B immunisation, including 'Action on children's virus risk "urgent"', *Dominion*, 22 September 1984; 'The fight against hepatitis: setting priorities', *Dominion*, 24 September 1984. The last article was a full-page spread in the Saturday edition.

<sup>120</sup> 'Editorial: Children at risk', *Dominion*, 5 October 1984.

policy ‘back burner’, argued that if the Department funded childhood immunisation in Kawerau, others towns would be likely to ask for similar support.<sup>121</sup>

Milne already had access to substantial community funding, and he ignored the Minister’s response. By early November 1984, he had completed the pilot study, which confirmed that a reduced dose of vaccine was effective against hepatitis B.<sup>122</sup> Presented with these results, Kawerau community leaders and medical practitioners unanimously approved the use of low dose vaccine for local children. The whole township was behind the project, despite the lack of government assistance.<sup>123</sup> The early union backing for the project minimised the need for public fund-raising but broad support from the entire community was evident. Schools held fundraising events, including coin trails and ‘spellathons’, three local ‘mothers’ raised \$8000 by approaching businesses and service clubs, the rugby football club raised \$800, and the milk vendors association presented ‘a generous cheque’ towards the cost of the vaccine.<sup>124</sup>

Once the project started, immunisations progressed rapidly.<sup>125</sup> In the local press, Winton Barnes, Medical Superintendent of Whakatane Hospital, described the town’s support for the programme as ‘unbelievable’ and the townspeople’s reaction as ‘exceptional’.<sup>126</sup> By early December 1984, Milne and a team of volunteer vaccinators had administered the first of three doses of vaccine to 90 per cent of the local schoolchildren, and a start had

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<sup>121</sup> Minister of Health to Milne, 24 January 1985, cited in W. Muraskin, ‘Bucking the health establishment: Alexander Milne and the fight for a New Zealand hepatitis B immunization program’, p.215. Health Department documents did, however, provide evidence of official interest in the use of low dose vaccine, which had the potential to provide an economical solution to hepatitis B prevention. In late October 1984, a memo prepared for Bassett stated that ‘widespread vaccination of “at risk” people is beginning to look feasible for the first time. The Health Department is actively monitoring this possibility’. Memorandum for the Minister of Health, ‘Hepatitis B Vaccine Studies’, 23 October 1984, cited in E. W. Pomare, ‘Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme’, p.7.

<sup>122</sup> ‘Children’s hepatitis vaccine success’, *Evening Post* (EP), 3 November 1984.

<sup>123</sup> E. W. Pomare, ‘Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme’, p.24.

<sup>124</sup> ‘Hepatitis fund needs donations’, *Whakatane Beacon*, 12 February 1985.

<sup>125</sup> Moyes ‘was absent during the pilot study of low dose vaccine and its first extension to Kawerau children’. C. D. Moyes, ‘A National Programme to Control Hepatitis B in an Endemic Area’, p.4.

<sup>126</sup> ‘Second round of vaccinations now underway’, *Kawerau Gazette*, 11 December 1984.

been made on immunising preschool children. By mid-December 1984, the second round of immunisations was underway.<sup>127</sup>

### **The first hepatitis B immunisation policy**

The publicity surrounding the Kawerau campaign excited public and professional interest in hepatitis B prevention. In late 1984 hepatitis B was not the only public health issue to compete for policy attention, however; AIDS was rapidly coming to the fore as a key priority for the Health Minister and the Health Department.

As the Kawerau campaign wound down, Alexander Milne announced his intention to expand the community-funded low dose immunisation programme to other parts of the Eastern Bay of Plenty.<sup>128</sup> His highly publicised campaign had captured both community and media attention. Interest in the New Zealand situation extended as far as Australia: in April 1985, Dr W. A. Langsford, President of the Australasian Society for Infectious Diseases, wrote to Mr G. Ansell, the New Zealand High Commissioner in Canberra, offering the services of the Society ‘in the absence of any concerted immunisation programme’.<sup>129</sup>

While Health Minister Michael Bassett was willing to consider a modest hepatitis B control programme, he regarded AIDS prevention as a more important public health priority.<sup>130</sup> AIDS first came to the attention of the New Zealand health authorities in mid-1981, when the CDC reported outbreaks of a mysterious illness affecting homosexual men in Los Angeles and New York.<sup>131</sup> The men developed Kaposi’s sarcoma, a cancer rarely seen in the US, and other fatal infections attributed to a breakdown in their immune

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<sup>127</sup> *ibid.* Vaccinators immunised 1395 primary and intermediate school children in the first phase of the programme.

<sup>128</sup> ‘All fourth forms next target in hepatitis testing’, *Whakatane Beacon*, 12 February 1985.

<sup>129</sup> Langsford to Ansell, 9 April 1985, ABQU 632 W4452/697 131/171/1 59858, ANZW.

<sup>130</sup> In an interview with the author, Michael Bassett explained that both AIDS and hepatitis B were minor issues compared with his efforts to restructure the health boards into area health boards, or to gain agreement on reducing doctor’s charges for child health consultations. M. Bassett, interviewed by D. M. Jowitt, 26 April 2008.

<sup>131</sup> CDC, ‘*Pneumocystis pneumonia* – Los Angeles’, *MMWR*, 30, 5 June 1981, pp.250-2; CDC, ‘Kaposi’s sarcoma and *Pneumocystis pneumonia* among homosexual men – New York City and California’, *MMWR*, 30, 3 July 1981, pp.305-7.

systems. Initially, AIDS appeared to be limited to the gay community, but by late 1982, reports emerged of the disease being transmitted through transfusion and injecting drug use. In New Zealand, in July 1983, the Health Department advised measures to protect people with haemophilia from blood products imported from the US, and in September 1983, AIDS was made a notifiable disease.<sup>132</sup>

During the first few months of Bassett's term as Health Minister, as a result of persistent lobbying on the part of the homosexual community, senior officials in the Health Department became convinced of the potential for AIDS to affect all sectors of New Zealand society.<sup>133</sup> Bassett responded positively to the Department's advice to act decisively on AIDS control. In November 1984, he announced he was sending doctors to the US and Australia to learn testing techniques for the human immunodeficiency virus (HIV), the causative agent for AIDS, and the following month he appointed an AIDS Task Force to advise the Health Department on a control strategy.<sup>134</sup> Despite the large financial deficit facing the government, Bassett also approved the introduction of HIV testing of donated blood, once commercial test kits became available. This measure was anticipated to cost more than half a million dollars per annum, a clear indication that AIDS had been designated as a key public health and political issue.<sup>135</sup>

During this period, Bassett formed close links with Neal Blewett, his ministerial counterpart in the Australian Labour Government.<sup>136</sup> Blewett took a pragmatic and innovative approach to AIDS prevention; as Paul Sendziuk explained, the Australian epidemic came to light eighteen months after that in the US, so that Blewett had the

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<sup>132</sup> Department of Health, Circular Letter No. Hosp 1983/82, 19 July 1983, 'Acquired immune deficiency syndrome and blood products', ZABV A1073 92a, ANZA; Department of Health, Circular Letter No. Hosp 1983/109, 12 September 1983, 'Acquired Immunodeficiency Syndrome (AIDS)', ZABV A1073 92a, ANZA.

<sup>133</sup> See for example, P. Parkinson, T. Hughes, 'The gay community and the response to AIDS in New Zealand'; E. Plumridge, J. Chetwynd, 'AIDS policy response in New Zealand: consensus in crisis'.

<sup>134</sup> AJHR, 1985, E.10, p.22.

<sup>135</sup> Ridings to Minister of Health, 'Proposals to minimise the spread of AIDS through the use of blood or blood products in New Zealand', 16 November 1984; Minister of Health to Chief Executives of all Hospital Boards and all Regional Transfusion Directors, 16 November 1984, Bassett papers, 89-329-02, ATL.

<sup>136</sup> Like Bassett, Blewett had been a university academic before he entered politics. M. Bassett, interviewed by D. M. Jowitt, 5 April 2007.

opportunity to observe the effects of ‘AIDS prevention policies constrained by moralism’.<sup>137</sup> Despite calls for extreme legislative measures against gay men, sex workers and drug addicts, all of whom the public regarded as responsible for the spread of AIDS, Blewett and his advisers developed an ‘education and empowerment model’ reliant on ‘the common sense, the tolerance and good will of ordinary people’ to control the spread of the disease.<sup>138</sup>

Bassett adopted this approach in New Zealand, where the first AIDS cases were coming to the attention of the Health Department.<sup>139</sup> In late 1984, public anxiety over the spread of the disease increased in response to reports of the exponential growth in cases in the US, and as a result of reports closer to home.<sup>140</sup> In November 1984 three Queensland babies died from AIDS after being transfused with blood donated by a gay man found to be HIV positive on subsequent testing. The deaths triggered a strong reaction among right-wing Australian politicians and religious leaders, who called for quarantining of the homosexual community to prevent the spread of the ‘gay plague’.<sup>141</sup> Even though the first ‘home-grown’ case of AIDS was not reported until July 1985, international events had a powerful effect on New Zealand health officials, and subsequently on politicians.<sup>142</sup> Early in April 1985, following a departmental briefing on the ‘potentially explosive situation with regards to AIDS’, the Labour Cabinet allocated almost \$3 million towards AIDS prevention programmes.<sup>143</sup>

With the political focus firmly on AIDS, Bassett gained a much smaller allocation for hepatitis B control during the 1985 budget round. In mid-April 1985, he announced the first hepatitis B immunisation policy. Hospital boards were to introduce antenatal

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<sup>137</sup> P. Sendziuk, *Learning to Trust: Australian Responses to AIDS*, pp.6-7.

<sup>138</sup> *ibid.*, p.135.

<sup>139</sup> AJHR, 1985, E.10, p.22. By March 1985, five AIDS cases had been notified to the Health Department. All of these people had acquired the disease overseas, and died soon after their return to New Zealand.

<sup>140</sup> CDC, ‘Update - Acquired Immunodeficiency Syndrome (AIDS) - United States’, MMWR, 32, 5 August 1983, pp.389-391; CDC, ‘Update: acquired immunodeficiency syndrome (AIDS) in persons with haemophilia’, MMWR, 33, 26 October 1984, pp.589-91.

<sup>141</sup> P. Sendziuk, *Learning to Trust: Australian responses to AIDS*, pp.56-60.

<sup>142</sup> Department of Health, News Release, 24 July 1985, Bassett papers, 89-329-02.

<sup>143</sup> Minister of Health, News Release, ‘AIDS Measures Released’, 11 April 1985, Bassett papers, 89-329-02.

screening for hepatitis B from September 1985, to identify women who were hepatitis B e antigen positive, and to provide protective vaccine and immunoglobulin for their babies. Bassett described this as the ‘first step in reducing and eventually eliminating the pool of infectious people’. The policy would have limited impact, however; it aimed to protect approximately 300 babies each year, at a cost of \$31,000 per annum.<sup>144</sup>

As a political strategy, the announcement fell short of expectations. It had little effect on the public’s perception that a more active stance should be taken against the virus, and the CDCAC later criticised it on the grounds that international guidelines recommended protection for the babies of all hepatitis B carrier mothers.<sup>145</sup> Milne had already taken the political limelight by organising the community-funded campaign in Kawerau, which vaccinated more than 1800 children at a cost of \$15 per child. Moreover, since early 1985, Milne and Moyes had instigated a policy of offering a course of low dose vaccine to all babies born in Whakatane and Kawerau.<sup>146</sup> To the public, particularly in the Bay of Plenty region, the cautious stance taken by the government compared negatively with Milne’s direct approach to the hepatitis B problem. Milne was predictably scathing of the policy; in the *Dominion* he expressed the opinion that it was ‘the one thing [the Government] could not avoid doing’.<sup>147</sup>

Thus, the Government’s first policy for hepatitis B immunisation met with a less than enthusiastic response. Milne had created an expectation that Bassett would extend state-funded hepatitis B immunisation to children, but instead, he delivered a policy that was too narrow to excite the public interest or to address the growing concerns over the spread of hepatitis B virus infection. By late 1984, AIDS was firmly established as the foremost public health focus of the Government and the Health Department, while hepatitis B was considered to be of relatively minor public health importance.

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<sup>144</sup> Minister of Health, News Release, ‘AIDS Measures Released’, 11 April 1985; News Release, Minister of Health, ‘Hepatitis B’, 18 April 1985, Bassett papers, ACC 89-329 Box 2, ATL; Department of Health, Circular Letter (Hosp) No. 1985/112, 18 April 1985, ‘Hepatitis B Immunisation of At-Risk Neonates’, ZABV A1073 96c, ANZA.

<sup>145</sup> CDCAC minutes, 29 August 1985, ABQU 632 W4452/701 131/171/4, ANZW.

<sup>146</sup> E. W. Pomare, ‘Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme’, p.51.

<sup>147</sup> ‘Researchers slam \$31,000 campaign for hepatitis B’, *Dominion*, 20 April 1985.



### **Controversy over the community-funded immunisation programme**

In early 1985, Alexander Milne gained the support of Bay of Plenty residents for an expansion of the community-funded immunisation programme to other parts of the region. However, his call for individual families to contribute to the cost of the low dose vaccine troubled members of the Maori community who believed that the Government should cover the costs of immunisation if hepatitis B was a serious health risk to their children. By approaching the Health Department to fund the community-based programme, the Maori Women's Welfare League elevated hepatitis B immunisation from a local concern to a national issue.

In early 1985, Alexander Milne and Chris Moyes conducted a survey of high school children in the Eastern Bay of Plenty which revealed that 'Hepatitis B infection was endemic ... with a substantial pool of carriers particularly amongst Maori children'.<sup>148</sup> In response to these findings, Milne and Moyes embarked on an intensive round of community education and consultation to seek the support of local communities for an expansion of the low dose immunisation programme.<sup>149</sup> In mid-June 1985, Whakatane community leaders unanimously approved a community-funded programme to immunise local children. There was palpable enthusiasm for the expansion of the scheme; fund raising plans were reported in local newspapers from Whakatane to Te Kaha.<sup>150</sup> Small towns such as Taneatua and Ruatoki did their best to match the donations from larger townships, including \$10,000 from the Whakatane District Council, and fund-raisers urged residents of the Bay of Plenty to give to the local vaccination programme rather than to the annual 'Telethon' appeal for children's health in late June 1985.<sup>151</sup>

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<sup>148</sup> C. D. Moyes, 'A National Programme to Control Hepatitis B in an Endemic Area', p.58. Moyes commented that 'As expected, the majority of non-European (i.e. Maori) children showed evidence of infection (60%), compared to half that rate in Europeans (30%), with a more than fivefold difference in prevalence of [hepatitis B carriage] (16% to 3%).'

<sup>149</sup> *ibid.*, p.116.

<sup>150</sup> 'Council grant recommended for Hepatitis vaccinations', *Kawerau Gazette*, 20 June 1986; 'Hepatitis \$6000 in fortnight is the aim', *Whakatane Beacon*, 26 June 1985; 'Taneatua aims for vaccine funding', *Whakatane Beacon*, 3 July 1985.

<sup>151</sup> 'Give money to hepatitis project not Telethon', *Whakatane Beacon*, 28 June 1985.

Amidst the enthusiasm for the programme, however, there was some disquiet. Maori communities contributed generously to the targets set for fund-raising, but they held deep concerns about their children's welfare. Many Maori believed that if their children were at such high risk of infection and longterm complications, the government should be covering the cost, as it did for other vaccines on the childhood immunisation schedule.<sup>152</sup> In late June 1985, Mrs Georgina Kirby, President of the Maori Women's Welfare League, and the Vice-President, Mrs Janet Brown, a resident of Whakatane, made representations to this effect to Dr George Salmond, Deputy Director-General of Health, stating furthermore that 'the large amounts of money that was being asked of the Maori communities would be a severe financial drain on a large number of poor families'.<sup>153</sup>

When the issue of hepatitis B was raised at the Board of Health Standing Committee on Maori Health on 4 July 1985, Salmond commented that 'hysteria' appeared to be developing among Bay of Plenty communities about the risks of hepatitis B virus infection among their children.<sup>154</sup> On the same day, Bassett issued a press release that was designed to calm the concerns of local residents. Noting the high prevalence of hepatitis B in the Eastern Bay of Plenty region, Bassett observed that although the Government had moved on the problem by announcing the introduction of protection for the babies of highly infectious carrier mothers, it appeared that local communities were being persuaded that their children were at 'grave risk' unless they were immunised against hepatitis B: 'However well meaning this may be, it is causing unjustified anxiety, verging on panic, among some parents.'<sup>155</sup> The following day, to further mollify public concerns, he added that 'There is no evidence to support claims that hepatitis B is a major cause of death or disability in New Zealand.'<sup>156</sup>

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<sup>152</sup> 'State tries to reassure Maori people', *Whakatane Beacon*, 3 July 1985.

<sup>153</sup> E.W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.7.

<sup>154</sup> Minutes of the Standing Committee on Maori Health, 4 July 1985, *ibid.*, p.8; p.94.

<sup>155</sup> Minister of Health, News Release, 'The Public Don't Need to Pay for Vaccination', 4 July 1985, *ibid.*, p.4.

<sup>156</sup> 'Bassett assails hepatitis campaign', *Dominion*, 5 July 1985.

In his attempt to allay community fears and respond to the concerns raised by Maori, Bassett unwittingly provoked public outrage. The local and national press represented the Minister of Health as ‘out of touch’ for minimising the hepatitis B problem in the Bay of Plenty.<sup>157</sup> Milne and Moyes described Bassett’s statements as ‘inaccurate and surprising’, while the Opposition MP for Tarawera, Ian McLean, challenged the Minister to resign ‘if ... he doesn’t like local initiatives to create good health’. In McLean’s view, hepatitis B in the Eastern Bay of Plenty ‘couldn’t increase much more with two-thirds of the population already having been infected at some stage of their lives’.<sup>158</sup>

Bassett responded to the growing furore by asking a prominent Maori physician, Dr Eru Pomare, Head of Gastroenterology at Wellington Hospital and Associate Professor of Medicine at the Wellington School of Medicine, to act as an independent investigator of the Bay of Plenty immunisation programme. As a member of the medical establishment and a leading Maori health researcher, Pomare was well-qualified for the role.<sup>159</sup> As Bassett later recalled, ‘[Pomare] had huge respect around the [Health] Department but he also had huge respect within Maoridom itself, and who better to do the study.’<sup>160</sup> On 9 July 1985, he confirmed Pomare’s appointment.<sup>161</sup> The editor of the *Dominion*, who described Pomare’s professional credentials as ‘impeccable’, welcomed this step.<sup>162</sup>

It was a politically astute appointment for an increasingly complex situation. Pomare himself observed that his ‘appointment led to an immediate reduction in the public arguments concerning the merits or otherwise of the hepatitis B campaign’.<sup>163</sup> He visited the Bay of Plenty twice, in mid and late August 1985. During these visits Pomare spoke first with hospital staff, members of the Hospital Board, and Milne, Moyes, and

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<sup>157</sup> ‘Bassett says concern over hepatitis B near panic’, *Bay of Plenty Times*, 5 July 1985; ‘Researchers defend hepatitis campaign’, EP, 5 July 1985; ‘Hepatitis vaccination defended’, *Dominion*, 6 July 1985.

<sup>158</sup> ‘Doctor Bassett is ‘out of touch’’, *Bay of Plenty Times*, 8 July 1985.

<sup>159</sup> Eru Pomare also came from a distinguished lineage. His grandfather, Maui Pomare, was the first Maori to gain a medical degree in 1900. After entering politics in 1911, he became Minister of Health in the Reform Government, 1923–1926.

<sup>160</sup> M. Bassett, interviewed by D. M. Jowitt, 5 April 2007.

<sup>161</sup> ‘Hepatitis B assessment’, *Whakatane Beacon*, 9 July 1985.

<sup>162</sup> ‘Funds for vaccine’, *Dominion*, 12 July 1985.

<sup>163</sup> E.W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.9.

pathologist Geoff Allwood, who together formed the ‘Hepatitis B Control Team’. He then travelled widely within the region to interview local people, and to observe the immunisation programme in action. Pomare found widespread support for the programme amongst Maori despite the costs to poorer families. While he remarked on Milne’s somewhat ‘evangelistic’ approach to preventing hepatitis B, Pomare acknowledged that without his ‘enthusiasm and drive, there would probably have been little positive action on the hepatitis B front in the Bay of Plenty’.<sup>164</sup>

Pomare took three months to prepare his report, which he delivered in late November 1985. Salmond later observed that ‘It took time but ... He sized the situation up in a way that we, using ordinary bureaucratic or departmental intelligence, could never have done’.<sup>165</sup> When it did come, its contents were somewhat unexpected.<sup>166</sup> As John Martin, Deputy-Director of Health (Administrative) from 1981 to 1987, explained, ‘when reports are requested by a bureaucracy it is on the understanding that the results are already anticipated’.<sup>167</sup> Pomare’s report not only endorsed the need for the vaccination programme, but it described hepatitis B as ‘an underestimated problem’ which was ‘currently New Zealand’s most serious viral infection’.<sup>168</sup>

Pomare praised the high quality of the research undertaken in the Bay of Plenty, which revealed a local problem for which a vaccination programme was the ‘logical step forward’.<sup>169</sup> He described the low-dose vaccination regimen as both safe and cost-effective, and recommended that the government should support the community-driven initiative, because in areas such as the Eastern Bay of Plenty ‘most children had been infected by the time they left school’. Furthermore, he estimated that there were between

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<sup>164</sup> E. W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p. 24; p.43.

<sup>165</sup> G. Salmond, interviewed by D. M. Jowitt, 25 November 2007.

<sup>166</sup> In Parliament, on 17 July 1985, Ian McLean, MP for Tarawera, challenged Bassett on the accuracy of his press statement questioning the seriousness of the hepatitis B problem in the Eastern Bay of Plenty. Bassett had replied that ‘I am sure Dr Pomare’s investigation will clear up the matter to my satisfaction’. NZPD, 17 July 1985, pp.5641-2.

<sup>167</sup> J. Martin, personal communication, 23 November 2007.

<sup>168</sup> E. W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.84; p.9.

<sup>169</sup> *ibid.*, p.52.

60,000 and 90,000 hepatitis B carriers in the New Zealand population.<sup>170</sup> In his opinion, the problem was so serious that ‘by world standards New Zealand can be bracketed with Third World Countries, such are the high rates of hepatitis B infection in certain areas’.<sup>171</sup> Pomare recommended that as ‘there is some urgency to protect those at high risk ... the Health Department [should] be responsible for implementing a more extensive and realistic immunisation programme than currently exists’. He also emphasised that ‘health initiatives involving Maori people [should] ensure Maori participation at all levels ... [and] that adequate resource support [should] be forthcoming to allow this to happen’.<sup>172</sup>

In response to the long-awaited report, Bassett announced he would seek approval from Cabinet for funds for a ‘wider’ immunisation campaign in the coming year. He referred the 104-page document, which he described as ‘longer than expected’, to his advisory committee for comment.<sup>173</sup> With Pomare’s endorsement of the low-dose immunisation programme, hepatitis B had moved up the policy agenda. At the end of 1985 Bassett found himself under increased political pressure to expand the hepatitis B immunisation programme.

## **Conclusion**

In the early 1980s, the Health Department regarded hepatitis B as an uncommon illness in New Zealand. Alexander Milne met strong resistance to his claims that infection was widespread in the Eastern Bay of Plenty, and that Maori children in particular, were at high risk of becoming hepatitis B carriers. Notwithstanding the negative response of health officials, Milne gained the support of a small group of medical specialists who proved influential in raising the profile of hepatitis B as a public health issue.

The introduction of a hepatitis B vaccine in 1982 raised the question of who should receive state-funded hepatitis B immunisation. The EAC recommended a targeted programme that focused on groups of ‘at risk’ infants and children, yet the Health

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<sup>170</sup> *ibid.*, p.57.

<sup>171</sup> *ibid.*, p.60.

<sup>172</sup> *ibid.*, p.90.

<sup>173</sup> ‘Hepatitis programme a “Step Forward”’, NZH, 30 November 1985.

Department was unwilling to formulate an immunisation policy. Its cautionary approach was not only a reaction to the high cost of the new vaccine. It was also a reflection of its reliance on WHO guidance on vaccine policy and of entrenched medical beliefs about the low prevalence of hepatitis B in New Zealand.

Milne's campaign for state-funded childhood hepatitis B immunisation was boosted by the results of the Kawerau study, which revealed that the disease was highly endemic among Maori and European residents of the town, and that the majority of infections occurred among children during their school years. Frustrated by the lack of official action on hepatitis B prevention, Milne initiated a successful community-funded childhood immunisation programme using low dose hepatitis B vaccine. When he and his supporters extended the low dose programme to other areas in the Eastern Bay of Plenty region, however, Maori leaders challenged the Government to fund the full costs of childhood hepatitis B immunisation.

The Health Minister, Michael Bassett, who considered hepatitis B to be a relatively minor health issue, brought matters to a head in mid-1985 by publicly questioning the need to immunise children against hepatitis B. By appointing Eru Pomare to investigate the community funded immunisation programme in the Eastern Bay of Plenty, Bassett anticipated that departmental views on the significance of hepatitis B would be confirmed. Instead, Pomare's report, which identified hepatitis B as a public health priority, put increased pressure on Bassett to expand the childhood hepatitis B immunisation programme.

## CHAPTER FIVE

### THE INTRODUCTION OF LOW DOSE HEPATITIS B VACCINE

1986–1987

In 1986, following Dr Eru Pomare’s high level support for the community-based hepatitis B immunisation programme in the Eastern Bay of Plenty, Alexander Milne’s campaign for state-funded childhood immunisation gained momentum.<sup>174</sup> Milne turned to international hepatitis experts and local media contacts to increase the pressure on the Health Minister, Michael Bassett, to expand the immunisation programme. To counter Bassett’s claims that the high cost of the hepatitis B vaccine prevented a more expansive hepatitis B policy, Milne promoted low dose hepatitis B vaccine as a thrifty and effective substitute for the full dose product. When Bassett indicated his intention to use low dose vaccine, however, the Communicable Disease Control Advisory Committee (CDCAC) protested that without sound scientific evidence of its efficacy, a low dose immunisation programme would be tantamount to a ‘nationwide experiment’ on New Zealand children.<sup>175</sup>

This chapter will consider how political priorities came to prevail over technical and legal advice in the formulation of hepatitis B policy. Milne, who will emerge as a key player, will be seen to exert an unexpected influence on the policy making process. The chapter will begin by discussing Milne’s strategy of inviting international medical experts to New Zealand to persuade senior public health officials and politicians of the urgent need for universal childhood hepatitis B immunisation. It will then consider his attempts to gain high level support for the use of low dose vaccine from Whakatane, a provincial town distant from the established nexus of health policy making. It will also examine reactions to the prospect of an ethnically-targeted immunisation programme, and the issues that

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<sup>174</sup> Pomare described the Eastern Bay of Plenty hepatitis B programme as ‘a unique community initiative that may well have application elsewhere’. E. W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.88.

<sup>175</sup> CDCAC minutes, 1 August 1986, Ministry of Health Archives, Wellington.

contributed to the decision to focus policy on high risk geographical areas, rather than high risk groups. Bassett's frugal approach to hepatitis B prevention will be seen to intersect with Milne's campaign for low dose childhood immunisation, and in the run up to the 1987 general election, to contribute to Bassett's decision to seek Cabinet approval to use low dose vaccine, despite expert advice to the contrary.

### **The power of international experts**

To strengthen his campaign for nationwide childhood immunisation, Alexander Milne drew on the authority of international experts in hepatitis B control. In doing so, he followed the model established by the Health Department in the 1950s, when the Department and its advisory committees had turned to the expertise and influence of the World Health Organization (WHO) for guidance on vaccine policy.<sup>176</sup> Milne took this strategy a step further, however, by bringing experts to New Zealand to meet with local politicians and public health officials.

Early in 1986, Milne invited three leading figures in hepatitis B research to New Zealand. Dr Ron Lucas, Chief of Medicine at Fairfield Infectious Diseases Hospital, Melbourne, Dr Mary Dimitrakakis, virologist at the Melbourne WHO Laboratory for Reference and Research on Viral Hepatitis, and Dr James Maynard, an expert advisor to WHO's hepatitis B programme and head of the Hepatitis Branch of the US Centers for Disease Control (CDC), arrived in Whakatane in mid-March 1986. Of the three, Maynard was the most prominent; William Muraskin described him as 'probably the most important public health official dealing with hepatitis problems in the world [in the 1970s and early 1980s]'.<sup>177</sup>

From Milne's perspective, he had timed their visit well. As Chapter Four discussed, Dr Eru Pomare's influential report on hepatitis B, which strongly endorsed the introduction

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<sup>176</sup> See A. S. Day, 'Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920–1990', pp.78-9, for further discussion of the Health Department's reliance on the WHO for advice and guidance on vaccine policy from the 1950s.

<sup>177</sup> W. Muraskin, *The War Against Hepatitis B: A History of the International Task Force on Hepatitis B Immunization*, p.26.



of a more 'extensive and realistic' childhood immunisation programme based on the use of low dose vaccine, had been delivered to the Health Minister in late 1985.<sup>178</sup> Moreover, the first data demonstrating the efficacy of low dose hepatitis B vaccine in children had been published in February 1986.<sup>179</sup> Lucas, a collaborator in the efficacy study, had shown strong support for Milne's research from the early 1980s, and had played an important part in promoting low dose vaccine to the Kawerau community in 1984. Dimitrakakis, a veteran of hepatitis B prevalence studies in the Pacific, also backed the use of low dose vaccine.<sup>180</sup>

Maynard was visiting New Zealand in a private rather than an official capacity, but he made himself available to meet with politicians and public health officials. While he was a strong advocate for universal childhood hepatitis B immunisation, however, Maynard had another solution to the prohibitive cost of the full dose vaccine. When he accompanied Milne to a meeting of the Medical Research Council (MRC) Working Party on Viral Hepatitis, he argued that the best way to lower prices was to register multiple vaccines. In his experience, commercial competition between pharmaceutical companies was the most effective way to reduce vaccine prices.<sup>181</sup> If more vaccines were registered, Maynard suggested, 'the need for continuing low dose evaluation, though interesting, was probably really unnecessary'.<sup>182</sup>

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<sup>178</sup> E. W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.88.

<sup>179</sup> A. Milne, G. K. Allwood, N. E. Pearce, C. R. Lucas, S. Krugman, 'Low dose hepatitis B vaccination in children', *NZMJ*, 99, 12 February 1986, pp.47-9. Over 90 per cent of the 134 children tested had developed antibodies to hepatitis B. Full dose vaccine produces immunity among at least 95 per cent of infants, children and adolescents. Ministry of Health, *Immunisation Handbook 2006*, p.131.

<sup>180</sup> See for example: T. Kuberski, G. Le Gonidec, I. D. Gust, M. Dimitrakakis, D. Cantaloube, P. Zimmet, 'Hepatitis B virus infections in Melanesians and Polynesians in New Caledonia', *American Journal of Epidemiology*, 114, 3, 1981, pp.355-61; A. Milne, M. Dimitrakakis, C. Campbell, C. R. Lucas, G. K. Allwood, P. Goldwater, N. E. Pearce, S. Krugman, 'Low-dose vaccination against hepatitis B in children: One-year follow-up', *Journal of Medical Virology*, 22, 1987, pp.387-92; A. Milne, M. Dimitrakakis, G. K. Allwood, C. R. Lucas, C. D. Moyes, N. E. Pearce, 'Immunogenicity of low doses of hepatitis B vaccine in children: A study in 650 New Zealand children', *Journal of Medical Virology*, 23, 1987, pp.401-5.

<sup>181</sup> In 1986, a three dose course of hepatitis B vaccine cost NZ \$75 per child.

<sup>182</sup> Minutes of the MRC Working Party on Viral Hepatitis, 24 March 1986, YCBN 5990 17b 11/6/11a/1 part 3 of 3, ANZA.

Maynard was a founding member of the International Task Force on Hepatitis B Immunization, which aimed to achieve mass immunisation in the developing world through the production of affordable hepatitis B vaccines.<sup>183</sup> Muraskin, who wrote an account of the Task Force's work in Asia, Africa, and the Middle East, explained how as soon as the first hepatitis B vaccine became available in 1982, Maynard 'quickly became convinced that universal childhood immunization rather than selective high-risk immunization was the only way to combat and eradicate the scourge of hepatitis B'. In his opinion, 'even in low endemicity countries ... only universal immunization would have any effect.'<sup>184</sup>

Predictably, Maynard disagreed with the narrow focus of New Zealand's hepatitis B immunisation policy.<sup>185</sup> In a meeting with the CDCAC, he argued that the Health Department's programme, which limited state-funded immunisation to the babies of hepatitis B e antigen positive mothers, would have little effect in containing the spread of hepatitis B, particularly in endemic areas like the Eastern Bay of Plenty. As the first step towards controlling the disease, he recommended an immunisation policy targeting all children less than 15 years of age in high prevalence health districts.<sup>186</sup> Furthermore, he reiterated his suggestion that competition between pharmaceutical companies would reduce the exorbitant prices charged for full dose vaccine.<sup>187</sup> Maynard's views were clearly influential: in the discussion that followed, the CDCAC agreed to form a Hepatitis Subcommittee to examine hepatitis B issues in more detail, and to prepare draft

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<sup>183</sup> The task force had been working in an informal alliance for several years before it was officially established on 28 April 1986. The other members were Dr Alfred Prince, an eminent New York and virologist hepatitis B researcher, Dr Ian Gust, a virologist at the Melbourne WHO Laboratory for Reference and Research on Viral Hepatitis, and Dr Richard Mahoney, Director of the US non-profit organisation Program for Appropriate Technology in Health. W. Muraskin, *The War Against Hepatitis B: A History of the International Task Force on Hepatitis B Immunization*, pp.19-53.

<sup>184</sup> *ibid.*, pp.29-30.

<sup>185</sup> CDCAC minutes, 27 March 1986, Ministry of Health Archives, Wellington.

<sup>186</sup> *ibid.*

<sup>187</sup> Muraskin explained that Maynard coined the term 'boutique vaccine' to describe the US hepatitis B vaccine marketed in Western countries, including New Zealand, at US\$100 per adult course, because he knew that by early 1985 the French pharmaceutical company, Pasteur Vaccins, had a contract to supply bulk hepatitis B vaccine to Taiwan for US \$4 per dose. *The War Against Hepatitis B: A History of the International Task Force on Hepatitis B Immunization*, pp.29-30.

recommendations for a more extensive immunisation programme.<sup>188</sup> In addition, it recommended that the Health Department should write to manufacturers to encourage the registration of at least one more hepatitis B vaccine in New Zealand.<sup>189</sup>

During their visit, Maynard and Lucas also met with the Minister of Health, Health Department officials, and Government caucus members.<sup>190</sup> Milne believed that these encounters were particularly effective in shaping the views of policy makers. In correspondence with Dr Jim Hodge, Director of the MRC, he claimed that together, Maynard and Lucas 'were able to persuade all that the problem of [hepatitis B virus] infections in New Zealand, particularly in the indigenous population, was indeed serious, and that it called for prompt action'.<sup>191</sup>

As a world-renowned authority on hepatitis B, Maynard's views were also of interest to the general public. Milne, who had cultivated a close relationship with the news media, ensured his visit received extensive press coverage. The Whakatane-based Hepatitis Research Unit (HRU) lacked the resources available to larger single-issue pressure groups, nevertheless, Milne more than made up for this by his flair for publicity and his ability to capture widespread interest in the hepatitis B debate.<sup>192</sup> For their part, the media willingly promoted his 'battle against bureaucracy', and the newsworthy views of his prominent supporters.

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<sup>188</sup> The subcommittee comprised of Dr Selwyn Lang, microbiologist at Middlemore Hospital, South Auckland, Dr Diana Lennon, paediatric infectious diseases specialist at Queen Mary Hospital, Auckland, and Dr Rod Ellis-Pegler, infectious diseases specialist, Auckland Hospital, and Chairman of the MRC Working Party on Viral Hepatitis.

<sup>189</sup> CDCAC minutes, 27 March 1986.

<sup>190</sup> Dimitrakakis attended the March 1986 CDCAC meeting with Maynard, Lucas and Milne, but appeared to have a shorter stay in New Zealand and less contact with health officials.

<sup>191</sup> Milne to Hodge, 'Control of hepatitis B in New Zealand children', 17 April 1986, YCBN 5990 17b 11/6/11a/1 part 3 of 3, ANZA.

<sup>192</sup> During the mid-1980s, on trips to Wellington, Milne sometimes stayed with Dr Don Matheson, a medical colleague from Whakatane Hospital, who later became Deputy Director-General of Public Health. Matheson remembered Milne as 'living and breathing' hepatitis B at this time: 'Every minute of the day he was working on the hepatitis B issue, ringing people, setting up situations to create publicity. He was highly skilled at creating an issue.' D. Matheson, interviewed by D. M. Jowitt, 20 August 2008.

A full page spread in the *Evening Post*, for example, carried the sensational header ‘WHO expert: NZ’s rate is at Third World level’. The article reported that Maynard considered that ‘the Eastern Bay of Plenty has the highest rate of infected European schoolchildren he has seen worldwide’ and that ‘the incidence of hepatitis B among Maori schoolchildren ranks with the world’s poorest and most underdeveloped nations’. According to the report, Maynard had advised the Minister of Health and the Health Department to plan a hepatitis B immunisation programme ‘as soon as possible’.<sup>193</sup>

An accompanying editorial, entitled ‘Scandalous neglect of health problem’, declared that ‘New Zealand has to devote more attention and money to the care of Maori children if it is to retain its self-respect as a caring society.’ The editor echoed Milne’s view that children should come first for hepatitis B vaccine, notwithstanding the risks faced by health care workers performing their daily duties: ‘Why should a Government department finance vaccine for dental nurses who are ... largely of European descent when children largely of Maori or Polynesian descent are sick or susceptible to infection too?’<sup>194</sup>

Thus, Maynard, Lucas and Dimitrakakis acted as powerful allies in Milne’s campaign for a childhood immunisation programme. Despite Maynard’s views on low dose vaccine, his emphatic support of childhood immunisation encouraged the CDCAC to make more forceful recommendations on hepatitis B policy, and influenced public opinion in favour of a more comprehensive immunisation programme. Moreover, as an expert advisor to the WHO and a senior CDC official, Maynard had the requisite qualifications to attract the attention of the Health Minister and senior health officials, as well as the news media, and to shape their views on hepatitis B control.

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<sup>193</sup> ‘WHO expert: NZ’s rate is at Third World level’, EP, 10 May 1986.

<sup>194</sup> ‘Editorial: Scandalous neglect of health problem’, EP, 10 May 1986. The editor was referring to the Government decision to fund hepatitis B immunisation for dental nurses on account of their ‘much higher risk level of contracting the illness’. Department of Health, Director-General’s Group, 3 September 1985, ‘Hepatitis B Vaccine Use’, 1985, ANZW.

### **Milne's campaign to promote low dose vaccine**

From Alexander Milne's perspective, it was more efficient to advance policy initiatives from outside of the central health bureaucracy, than to engage in protracted discussions with Health Department officials. The 1982 Whakatane workshop, discussed in Chapter Four, had simultaneously raised the profile of hepatitis B as a public health problem and confirmed Milne's status as a key hepatitis B researcher. To maintain the impetus of Maynard and Lucas' visit, Milne proposed another scientific meeting in Whakatane, both to stimulate policy debate and to promote the merits of low dose hepatitis B vaccine.

In April 1986, Milne wrote to Dr Jim Hodge, Director of the MRC, to seek his support in bringing a range of medical specialists, health officials, and interested observers to Whakatane to produce 'a practical plan' to protect children from hepatitis B. As an extra fillip, he informed Hodge that Professor Saul Krugman, a renowned authority on hepatitis B in childhood and a staunch supporter of low dose vaccine, had agreed to attend.<sup>195</sup>

Krugman, Professor of Paediatrics at New York University, played a central role in the early development of hepatitis B vaccine. During the 1960s and early 1970s, while paediatrician to the Willowbrook School, a residential institution for intellectually impaired children in New York City, Krugman conducted research into viral hepatitis and produced a basic, but surprisingly effective, proto-vaccine against hepatitis B.<sup>196</sup> Ethical aspects of his hepatitis studies at Willowbrook attracted controversy in the mid-1970s; nevertheless, the US medical establishment had honoured him for his pioneering work on the hepatitis B vaccine, and he was widely regarded as an expert on hepatitis B immunisation in childhood.<sup>197</sup> In 1984, as the previous chapter discussed, Krugman had advised Milne to trial the use of low dose vaccine in Kawerau, as a means of providing low cost hepatitis B immunisation for local children.

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<sup>195</sup> Milne to Hodge, 17 April 1986, YCBN 5990 17b 11/6/11a/1 part 3 of 3, ANZA.

<sup>196</sup> S. Krugman, J. P. Giles, J. Hammond, 'Viral hepatitis, type B (MS-2 strain): Studies on active immunization', *JAMA*, 217, 1, 5 July 1971, pp.41-5.

<sup>197</sup> S. Krugman, 'The Willowbrook Hepatitis Studies Revisited: Ethical Aspects', *Reviews of Infectious Diseases*, 8, 1, January–February 1986, pp.157-62; W. Muraskin, 'The Willowbrook experiments revisited: Saul Krugman and the politics of morality', unpublished paper, private possession.

Milne's innovative attempts to influence the policy process were in direct contrast with the more measured approach taken by the Health Department's advisory committees. The CDCAC and the MRC Working Party on Viral Hepatitis, predominantly composed of medical specialists, adhered closely to established protocols of policy making in the expectation that their recommendations on childhood immunisation would eventually impact on hepatitis B policy. By early 1986, however, they were beginning to have doubts about their effect on the decision making process. In April 1986, Dr Roderick (Rod) Ellis-Pegler, an infectious diseases specialist at Auckland Hospital and a member of both the CDCAC and the MRC Working Party on Viral Hepatitis, wrote to the Director-General of Health, Dr George Salmond, questioning the value placed on the advice offered by these committees. As he explained, 'there is little evidence that the Department felt the suggestions were of any merit if we judge that evaluation by subsequent departmental actions'.<sup>198</sup> In reply, Salmond blamed departmental inaction on the high cost of the hepatitis B vaccine and the demands posed by more pressing public health projects: 'any failure to implement your suggestions was more related to resource constraints and competing programme requirements than your recommendations lacking merit'.<sup>199</sup>

There is no doubt that the Health Department faced severe financial restraints. In mid-1986, Health Minister Michael Bassett introduced cuts in the department's operational expenditure, which limited the funds available for public health projects. The balance of payments crisis that had confronted the Fourth Labour Government in mid-1984 continued to pose major challenges for Roger Douglas, the Minister of Finance, who was determined to reduce the fiscal deficit before the July 1986 Budget.<sup>200</sup> The focus on cost-reduction inevitably impacted on operational activities; to achieve financial efficiencies in the health sector, Salmond was charged with the 'fundamental restructuring' of the Health Department, which according to his senior administrator, John Martin, led to

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<sup>198</sup> Ellis-Pegler to DGH, 14 April 1986, YCBN 5990 17b 11/6/11a/1 part 3 of 3, ANZA.

<sup>199</sup> DGH to Ellis-Pegler, 28 April 1986, YCBN 5990 17b 11/6/11a/1 part 3 of 3, ANZA.

<sup>200</sup> In his memoir of the Fourth Labour Government, Bassett described a 'cabinet "razor gang"' that 'went to work [in April 1986] slashing bits of government expenditure deemed dispensable'. M. Bassett, *Working with David: Inside the Lange Cabinet*, p.208.

‘some uncertainty about responsibilities in the area of communicable disease control’.<sup>201</sup> Furthermore, the dominant view within the Government and the Health Department that AIDS was a more important public health priority than hepatitis B ensured that the majority of discretionary funding was allocated for AIDS prevention programmes.<sup>202</sup>

Despite his preoccupation with the AIDS issue, however, Bassett was cognisant of the evidence of widespread hepatitis B virus infection in New Zealand, and of the growing public pressure for a childhood hepatitis B immunisation policy. In early June 1986, at the Minister’s request, the CDCAC considered the options for expanding the hepatitis B immunisation programme.<sup>203</sup> The committee recommended a dual approach to childhood immunisation: universal infant immunisation and a five year ‘catch-up’ campaign for school children at entry to primary and intermediate school. If a nationwide programme proved too costly, the CDCAC recommended targeting high prevalence areas in the North Island to ensure that those babies and children at highest risk of infection received immediate protection. The CDCAC recognised the difficulties posed by the high cost of the hepatitis B vaccine; nevertheless, it did not consider the use of a lower than recommended dose to be an appropriate solution. With scant scientific data available to support the efficacy of low dose vaccine, the CDCAC envisaged that the state-funded immunisation programme would be based on the full dose product.<sup>204</sup>

Within a week of receiving the CDCAC’s advice, Bassett announced an expansion of the hepatitis B immunisation programme. The new policy had a narrower focus than the CDCAC had recommended but Bassett had clearly signalled the political importance of the hepatitis B issue to his Cabinet colleagues. In the July 1986 budget, he gained additional expenditure of \$3,165,000 for hepatitis B control over three years; \$600,000 for the remainder of the 1986/87 financial year and \$2,565,000 for the two years from

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<sup>201</sup> As Salmond observed in his annual report to Parliament in early 1987, ‘Such large scale change would have been easier had [it] come at a time of expanding rather than shrinking resources’. AJHR, 1987, E.10, p.3; p.10; J. Martin, ‘The Low Dose Decision’, July 1988, private papers, J. Martin.

<sup>202</sup> By comparison, in the July 1986 Budget, Cabinet allocated \$9.9 million to AIDS-prevention over the following three years. Minister of Health, News Release, ‘Reflections on the Health Portfolio - 1986’, 26 December 1986, Bassett papers, 88-289-6, ATL.

<sup>203</sup> CDCAC minutes, 12 June 1986, Ministry of Health Archives, Wellington.

<sup>204</sup> *ibid.*

April 1987.<sup>205</sup> The expanded programme would provide full dose immunisation for the babies of all hepatitis B carrier mothers, and for all newborn babies born in three or more high prevalence health districts. Bassett acknowledged the CDCAC in his decision, stating that their recommendations ‘had [been] taken into account’, but the CDCAC and its predecessor, the Epidemiology Advisory Committee, had been advocating urgent action on hepatitis B control since late 1983. If hepatitis B had finally moved up the political agenda, it was not in response to their earnest recommendations and technical expertise. It had emerged as an important public health issue as a result of Eru Pomare’s hard-hitting 1985 report, Milne’s persistent campaign for childhood immunisation, the well-publicised views of international experts, and growing community interest in hepatitis B prevention.

The Whakatane meeting, which took place in mid-July 1986, further amplified Milne’s influence on policy development. Twenty-nine participants attended, two of whom were from the Health Department, as well as fourteen observers, including three MPs from local electorates.<sup>206</sup> The meeting focused on prevalence studies undertaken in the Eastern Bay of Plenty, and local research on the efficacy of the low dose hepatitis B vaccine.<sup>207</sup> These studies, which were based on relatively small groups of babies and children, had obvious scientific limitations; nevertheless, they met with a positive reception. In correspondence with Hodge, Milne suggested that ‘Professor Krugman’s endorsement of the low dose programme may have been a deciding factor in the acceptance of our data.’<sup>208</sup>

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<sup>205</sup> M. Bassett, *Working with David: Inside the Lange Cabinet*, p.208; Minister of Health, News Release, ‘Bassett announces increased funding for hepatitis B immunisation’, 19 June 1986, Bassett papers, 88-289-61, ATL.

<sup>206</sup> Paul East, National MP for Rotorua, Ian McLean, National MP for Tarawera, and Anne Fraser, Labour MP for East Cape attended as observers.

<sup>207</sup> C. D. Moyes, A. Milne, M. Dimitrakakis, P. N. Goldwater, N. E. Pearce, ‘Very-low-dose hepatitis B vaccine in newborn infants: an economic option for control in endemic areas’, *Lancet*, 329, 8523, 3 January 1987, pp.29-30; P. N. Goldwater, D. G. Woodfield, ‘Successful short course for intradermal hepatitis B vaccine’, *NZMJ*, 97, 26 December 1984, pp.905-6; P. N. Goldwater, D. G. Woodfield, A. M. Ramirez, I. Steed, ‘Intradermal, low dose, short course hepatitis B vaccination’, *NZMJ*, 99, 24 September 1986, pp.703-5.

<sup>208</sup> Milne to Hodge, 21 July 1986, YCBN 5990/18b 11/6/11b, ANZA.



Milne's assessment appeared to be accurate; Dr John Holden, Director of the Health Promotion Division, and Dr Arvind Patel, the Assistant Director, who attended the meeting as Health Department representatives, were apparently among those persuaded by Krugman of the efficacy of low dose vaccine. Bassett, who recognised the financial merits of the low dose option, was more than willing to consider their views. On 20 July 1986, three days after the Whakatane meeting, he proposed low dose vaccine as a means of expanding the hepatitis B immunisation programme.<sup>209</sup>

Bassett's about-turn on vaccine policy took his advisory committees by surprise. On 23 July 1986, Dr Cliff Tasman-Jones, a member of the MRC Working Party on Viral Hepatitis, wrote to Hodge, reflecting on the unexpected influence Milne had exerted on the policy making process. Tasman-Jones, who had attended the first day of the Whakatane meeting, stated that 'It looks as though [the low dose recommendation] has been used in a very strong way to put political pressure on the Minister of Health and he is accepting [it] as a basis for formulating policy'.<sup>210</sup> From Tasman-Jones' perspective, the technical expertise of the advisory committees had been side-lined in decision making: 'It is interesting that this sort of pressure can come from a group ... not informed sufficiently to make the decision, whereas groups set up particularly to advise on this [matter] do not have the same political impact'.<sup>211</sup> Hodge agreed that he, too, had been 'bemused by the apparently uncritical acceptance of the low-dose recommendation, without a requirement for evidence of efficacy'.<sup>212</sup> He wrote to Salmond to express his concerns, and to pass on Tasman-Jones' view that the recommendation to adopt the use of low dose vaccine should have been referred to the MRC Working Party for its consideration.<sup>213</sup>

Salmond, meanwhile, had already approached Holden to investigate the use of low dose vaccine. In response, Holden informed him that a special meeting of the CDCAC had

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<sup>209</sup> CDCAC minutes, 1 August 1986.

<sup>210</sup> Tasman-Jones to Hodge, 23 July 1986, YCBN 5990/18b 11/6/11b, ANZA.

<sup>211</sup> *ibid.*

<sup>212</sup> Hodge to Tasman-Jones, 28 July 1986, YCBN 5990/18a 11/6/11a/1, ANZA.

<sup>213</sup> Hodge to DGH, 29 July 1986, YCBN 5990/18a 11/6/11a/1, ANZA.

been scheduled for 1 August 1986, to consider the Minister's proposal. Holden, who had previously expressed strong views on the relative importance of hepatitis B and AIDS as public health problems, appeared to be having second thoughts on the low dose proposal.<sup>214</sup> While he provided the comparative costs of implementing the expanded programme of immunisation using both the full dose and the low dose vaccine, he stated that it was his belief that a 'rational' system of policy making should prevail over pressure group politics: 'it is upon the expert advice of that committee that a decision on low dose must ultimately rest'.<sup>215</sup>

As it was, the CDCAC held mixed views on the proposal. After considerable discussion at their meeting in early August 1986, the committee took a vote: four members voted for the use of low dose vaccine, and five against. On this basis, the committee recommended that 'more funds should be allocated by the government to ... enable a national programme to be undertaken properly'. The majority opinion was that 'there was insufficient evidence to proceed with a national hepatitis B immunisation programme using lower than the manufacturer's recommended doses of vaccine'. Furthermore, the committee agreed that 'if a lower dose was used, it should be regarded as a nationwide experiment that could not be controlled, monitored or properly administered'.<sup>216</sup>

The Health Department's Medicines and Benefits Unit also opposed Bassett's proposal, but on legal grounds. It advised the Minister that changing the manufacturer's recommended dose of vaccine would be in breach of Section 24 of the 1981 Medicines Act, which did not authorise the Minister of Health, or any Health Department official, to recommend the use of a medicine in doses that differed from the terms of its original registration. While an individual doctor could change the dose of a medicine according to

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<sup>214</sup> Holden's response to Salmond suggests that it may have been Patel who was more enthusiastic about the use of low dose vaccine. In a *NZ Listener* interview in August 1985, Holden had expressed the view that AIDS was the more important public health problem facing New Zealanders, and that the Health Department would proceed with its hepatitis B immunisation programme 'as finances allowed'. L. Guerin, 'Undercover epidemic', p.16-8.

<sup>215</sup> Holden to DGH, 28 July 1986, 'Expanded hepatitis B immunisation programme', ABQU 632 W4452/697 131/171/1 61469, ANZW.

<sup>216</sup> CDCAC minutes, 1 August 1986.

his professional judgment, this provision did not apply to the Health Department, which the law regarded as a ‘monitor’, not a ‘user’ of registered medicines.<sup>217</sup>

In the face of such strong resistance, Bassett acquiesced to his advisors, even though he was clearly tempted by the low dose proposal. Quite apart from the public health benefits of an immediate start on nationwide childhood hepatitis B immunisation, there were political and fiscal advantages to the use of low dose vaccine.<sup>218</sup> As he later recalled, ‘Funding was tight, and I was desperate to try to get something done with the minimal resources I had at my command ... if there was anything in the low dose option, I would have wanted it fully explored’.<sup>219</sup> While the official focus remained on the delivery of full dose hepatitis B vaccine to babies in high risk health districts, Bassett still held hopes of a further expansion of the immunisation programme. Despite his enthusiasm for low dose vaccine, however, the CDCAC would not budge. At its next meeting in mid-September 1986, Bassett requested further discussion on the low dose proposal, but the CDCAC saw no reason to change its previous stance on the low dose hepatitis B vaccine.<sup>220</sup>

It is clear then, that Milne exerted a powerful influence on policy makers from outside of ‘the corridors of power’. Notwithstanding the reservations of his technical advisors, Krugman’s strategic support convinced the Health Minister of the financial and political benefits of a low dose immunisation programme. On the advice of Health Department officials and the CDCAC, Bassett set aside the low dose proposal, but he did so reluctantly; he clearly considered low dose vaccine to be a fiscally viable solution to a pressing political problem and an increasingly significant public health issue.

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<sup>217</sup> R. C. Riseley, ‘Hepatitis B Vaccine in Low Doses’, 31 July 1986, ABQU 632 W4452/665 131/171/4 63302, ANZW.

<sup>218</sup> Bassett received letters from senior paediatricians in Hamilton and Rotorua expressing strong support for the immediate introduction of a low dose immunisation programme for children. Cull to Minister of Health, 6 August 1986; Morreau and Miles to Minister of Health, 8 August 1986; ABQU 632 W4452/697 131/171/4 61470, ANZW.

<sup>219</sup> M. Bassett, interviewed by D. M. Jowitt, 26 April 2008.

<sup>220</sup> CDCAC minutes, 18 September 1986, Ministry of Health Archives, Wellington.

## **Delta virus**

During 1986, the issue of delta virus, or hepatitis D virus, gained importance in deliberations over hepatitis B policy. Infection with delta virus, which only occurs in people infected with hepatitis B virus, can cause more severe liver disease than would result from hepatitis B virus infection alone. While the high cost of hepatitis B vaccine dominated the immunisation debate, Eru Pomare's warning that 'the introduction of the Delta agent into endemic areas [of New Zealand] could be catastrophic' had a salutary effect on health officials.<sup>221</sup> Fears of an outbreak of hepatitis D virus infection in communities with a high prevalence of hepatitis B added urgency to plans for the expansion of the immunisation programme.

In his November 1985 report to the Minister of Health, Eru Pomare explained that delta virus co-infection was a potentially serious disease which could transform asymptomatic hepatitis B carriage from a mild condition to a severe or fatal illness in a relatively short time. The prevalence of delta virus in New Zealand was unknown, as the disease had only been identified in 1977, nevertheless, Pomare believed that the introduction of 'Delta super-infections ... into endemic areas such as the Eastern Bay of Plenty could have disastrous consequences'. He recommended that prevalence studies of delta virus co-infection should be carried out, either during a serum survey conducted by the National Health Institute (NHI), or from the 'substantial bank of blood samples' stored by Milne in the Hepatitis Research Unit, in its laboratory facility located on the Whakatane Hospital premises.<sup>222</sup>

In the mid-1980s, few studies on the prevalence of delta co-infection had been undertaken. A 1984 survey of Nauruans, Niueans and Western Samoans published by Mary Dimitrakakis and fellow virologist Dr Ian Gust found that over 28 per cent of those surveyed had been infected with the virus, suggesting that it was likely to be present in

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<sup>221</sup> E. W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.84.

<sup>222</sup> *ibid.*, pp.65-6; p.81.

other Pacific Island groups.<sup>223</sup> The same year, outbreaks of delta co-infection in Venezuela and the US highlighted the need to protect hepatitis B carriers.<sup>224</sup>

The NHI reported the first case of fatal delta co-infection in New Zealand in February 1986. Blood donor data suggested more deaths might follow. At the March 1986 meeting of the MRC Working Party on Viral Hepatitis, Graeme Woodfield, Director of the Auckland Blood Transfusion Service, presented the preliminary results of a survey in the Auckland region that showed evidence of past or present delta infection among two per cent of European and 22 per cent of Pacific hepatitis B carriers.<sup>225</sup> While no Maori carriers were affected, Woodfield's findings caused increased concern that delta hepatitis could become a significant public health problem in New Zealand.<sup>226</sup> In April 1986, in a letter to Jim Hodge, Director of the MRC, Rod Ellis-Pegler drew attention to Woodfield's data and the increased risk of severe liver disease among people chronically infected with hepatitis B: 'The theoretical potential for catastrophe should this agent infect the huge numbers of indigenous New Zealand carriers is obvious.'<sup>227</sup>

It is difficult to assess the degree to which these concerns shaped the development of hepatitis B policy, nonetheless, Dr Alexander (Sandy ) Simpson, Michael Bassett's medical secretary from 1984 to 1986, recalled that delta co-infection was considered a potentially serious problem that could be prevented by universal childhood hepatitis B immunisation.<sup>228</sup> Delta co-infection was still considered a significant issue in 1987; when Woodfield and his colleagues published the results of their serum survey, they described it as a disease that could spread in an epidemic form, and recommended widespread

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<sup>223</sup> M. Dimitrakakis, I. D. Gust, 'Letter to the editor: Delta infection in Pacific Islanders', *Medical Journal of Australia*, 4 August 1984, p.197.

<sup>224</sup> S. Hadler, M. Monzon, A. Ponzetto 'Delta virus infection and severe hepatitis: an epidemic in the Yuca Indians of Venezuela', *Annals of Internal Medicine*, 100, 1984, pp.339-44; CDC, 'Delta hepatitis – Massachusetts', *MMWR*, 33, 7 September 1984, pp.493-4.

<sup>225</sup> Minutes of the MRC Working Party on Viral Hepatitis, 24 March 1986, YCBN 5990 17b 11/6/11a/1 part 3 of 3.

<sup>226</sup> M. Tobias, R. Oxner, M. Schousboe, H. B. Cook, 'Letter to the Editor: Hepatitis D in New Zealand', *NZMJ*, 99, 12 February 1986, p.66.

<sup>227</sup> Ellis-Pegler to Hodge, 14 April 1986, YCBN 5990 17b 11/6/11a/1 part 3 of 3, ANZA.

<sup>228</sup> A. Simpson, personal communication, 21 March 2007.

vaccination against hepatitis B as a preventive measure.<sup>229</sup> Furthermore, the memorandum presented to Cabinet by Bassett in mid-June 1987 to seek funding for a national hepatitis B immunisation programme highlighted it as a potentially serious public health issue. This document described wider immunisation against hepatitis B as ‘the only way to prevent delta hepatitis gaining a foothold [in New Zealand]’.<sup>230</sup>

In summary, in 1986 and 1987, health officials and senior health advisors considered delta virus to be a potentially serious health threat to hepatitis B carriers in endemic areas of New Zealand. While it was not an overriding consideration in policy development, concerns over delta virus co-infection contributed to the pressure to provide a more comprehensive state-funded hepatitis B immunisation programme.

### **Ethnicity as a policy determinant**

The high prevalence of hepatitis B carriage among Maori children raised the possibility of an ethnically-targeted immunisation policy. Attempts to single out Maori children for vaccine had caused controversy in the past, however, and the Health Department was wary of introducing a programme that exacerbated racial tensions.<sup>231</sup> Moreover, while ethnicity was an important factor in the epidemiology of hepatitis B in New Zealand, geographical location also impacted on prevalence rates.

In mid-1986, the preliminary results of a National Serum Survey among 3000 New Zealand children became available to the CDCAC and senior health officials. By fifteen years of age, eight per cent of European and 42 per cent of Maori children throughout the country had evidence of past or present hepatitis B virus infection. This survey corroborated both Milne’s findings in the Eastern Bay of Plenty and an earlier survey

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<sup>229</sup> A. M. Ramirez, S. P. Lee, D. G. Woodfield, ‘Hepatitis delta virus infection: a recently imported disease in New Zealand’, NZMJ, 100, 22 April 1987, pp.235-7.

<sup>230</sup> Office of the Minister of Health, Memorandum for Cabinet, ‘National Hepatitis B Immunisation Programme’, 18 June 1987, ABQU 632 W4452/702 131/171/4 62752, ANZW.

<sup>231</sup> See A. S. Day, ‘Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920–90’, pp.51-3; pp.96-102; pp.196-8, for further discussion of the Health Department’s controversial policies on typhoid immunisation and the use of the BCG vaccine for Maori children.

conducted by NHI scientists.<sup>232</sup> On the face of it, these figures suggested that there might be some merit in an ethnically-targeted immunisation programme. However, even though Maori children had high hepatitis B prevalence rates, infection rates among European children were also significant, particularly in the North and East of the North Island, in areas where there were proportionately more Maori living. As Neil Pearce explained, even though hepatitis B was five to ten times more common in Maori than in non-Maori, there were ‘five to ten times more Pakeha than there were Maori ... So you if looked at the limited information available from national surveys, more than half the carriers in the country were Pakeha’.<sup>233</sup>

International experts in hepatitis B, who were fascinated by the high prevalence of infection among both Maori and European children in the Eastern Bay of Plenty, believed the extent of hepatitis B virus infection among European children to be unique among developed countries.<sup>234</sup> The first locally-made television documentary on hepatitis B screened on ‘Eyewitness News’ in late July 1986, less than a fortnight after the Whakatane meeting. In the documentary, Ron Lucas, Head of Medicine at Fairfield Infectious Diseases Hospital, Melbourne, claimed that:

New Zealand is unlike any other Western country ... [While the hepatitis B prevalence in] Maori people is no different from other indigenous South Pacific people, the difference in New Zealand is that there has been a great spill over effect into European children.<sup>235</sup>

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<sup>232</sup> M. Tobias, J. A. Miller, C. J. Clements, A. C. Patel, ‘Hepatitis B in New Zealand children: the 1985 national immunization survey’, NZMJ, 100, 8 April 1987, pp.203-6; Y. E. Hermon, I. K. Mushawar, M. I. Tobias, ‘Hepatitis B infection in New Zealand children’, NZMJ, 97, 26 December 1984, pp.887-9.

<sup>233</sup> In Pearce’s opinion ‘any strategy that said it was [only] a Maori disease ... would only pick up half the cases, so you were basically doomed to failure’. N. E. Pearce, interviewed by D. M. Jowitt, 9 February 2007.

<sup>234</sup> Ron Lucas, for example, said that ‘the thing that absolutely fascinated me was how different hepatitis B was from what our experience was in Australia’. He also referred to hepatitis experts in the US being ‘fascinated’ by the Kawerau study and subsequently having a strong interest in coming to Whakatane. C. R. Lucas, interviewed by D. M. Jowitt, 9 July 2007.

<sup>235</sup> ‘Eyewitness News’, TVNZ, 28 July 1986, P20116, TVNZ Archives, Wellington.

'Eyewitness News' reached a wide viewing audience, as evidenced by the sudden increase in correspondence and telephone calls to district offices of the Health Department. While the documentary did not allude to the Health Minister's intention to limit state-funded hepatitis B immunisation to babies born in high prevalence areas, public health officials were clearly concerned by the implications of the new policy. High prevalence districts were essentially synonymous with geographical areas with large Maori populations, where the infection risk for European children was also relatively high. For the general public, however, the finer details of hepatitis B epidemiology were of less interest than the widely-held expectation that New Zealanders should enjoy equal access to publicly funded health services. In a memo to George Salmond, the Director-General of Health, Dr E. Hickin, Medical Officer of Health for Palmerston North, wrote that, following the 'Eyewitness' programme his office had received a large number of phone calls from very concerned parents who wanted their children immunised, and 'it may be seen as discrimination if only [children in] certain districts were able to receive vaccinations'.<sup>236</sup>

The targeted immunisation policy was intended to provide vaccine for those at most risk of hepatitis B virus infection, but not everyone was convinced it would bring health benefits. Some Maori feared that immunisation would put their children at greater risk of acute hepatitis B infection later in life. Writing to Health Minister Michael Bassett in October 1986, Dr Peter Sharples, Chairman of Te Runanga O Ngati Kahunguru, referred to a statement made by Hawke's Bay infectious diseases physician Dr Richard Meech, that childhood vaccination might only give limited protection resulting in 'a mere postponement of the disease'.<sup>237</sup> Sharples asked Bassett why the vaccine was being promoted when doubt remained as to its efficacy: 'It appears that Bay of Plenty Maori children are being used as Guinea Pigs on the very shaky moral grounds that the incidence of Hepatitis B amongst them is high.'<sup>238</sup>

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<sup>236</sup> Health Department, Inter-Office Memo, 'Expanded hepatitis B immunisation programme', 31 July 1986, ABQU 632 W4452/701 131/171/4 64435, ANZW.

<sup>237</sup> 'Hepatitis B greater immediate threat than AIDS', *Hawke's Bay Herald-Tribune*, 16 August 1986.

<sup>238</sup> Sharples to Minister of Health, 16 October 1986, ABQU 632 W4452/701 131/171/4 64435, ANZW.



Meech, a member of the CDCAC, had argued for an ethnically-targeted hepatitis B vaccination programme at the committee's meeting in September 1986. While this approach appeared to have some merit as a means of addressing the high prevalence of hepatitis B among Maori, it raised the sensitive issues of racial stigmatisation and preferential funding on the basis of ethnicity. When the CDCAC asked Eru Pomare, Professor of Medicine at the Wellington School of Medicine, for his opinion, he expressed strong reservations about such a policy:

To target an immunisation programme on Maoris and Polynesians would, of necessity, deprive the non-Maori sector of immunisation, which I believe is unjustified ... whilst this problem has been highlighted for Maori children, the problem among non-Maoris is also extraordinarily high ... The second reason I would not favour an ethnically directed immunisation programme is that this would unnecessarily emphasise racial differences and what might be seen as preferential treatment. These are difficult times with respect to race relations, and I would suspect strong protestations from the non-Maori community at such an approach.<sup>239</sup>

Pomare had long advocated Maori participation in health programmes involving Maori people, not only to minimise 'misunderstanding and cultural insensitivity', but also to promote Maori autonomy in health care.<sup>240</sup> Despite his misgivings about an ethnically-targeted immunisation policy, he added that he would be willing to consider this approach if Maori initiated the programme: 'if such an initiative were to come from Maori groups ... that would be somewhat different to the situation where Maori people were being told what was good and necessary for them'.<sup>241</sup>

In early December 1986, Bassett announced that the babies of carrier mothers throughout the country as well as all newborn babies in six health districts and one health area in the

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<sup>239</sup> This letter echoed the views that Pomare had already expressed in his 1985 report to the Health Minister, in which he recommended against a 'Maori only [immunisation] programme'. E. W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.89; Pomare to CDCAC, 1 December 1986, ABQU 632 W4452/701 131/171/4 61770, ANZW.

<sup>240</sup> E. W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.90.

<sup>241</sup> Pomare to CDCAC, 1 December 1986, ABQU 632 W4452/701 131/171/4 61770, ANZW.

North Island, were to be offered hepatitis B immunisation. The districts designated as 'high risk' were areas with large Maori populations: Northland, Auckland, South Auckland, Rotorua, Napier, and Gisborne.<sup>242</sup> In view of the high prevalence of hepatitis B in the north and east of the North Island, this policy had a sound scientific basis. Nevertheless, it did not meet the expectations of the general public that public health programmes should be delivered nationally, and that there should be equity of access, regardless of race, income, or social standing.

### **Milne maintains pressure for childhood immunisation**

Throughout 1986 and early 1987, Alexander Milne maintained his single-minded campaign to promote low dose childhood hepatitis B immunisation. While his supporters marvelled at his determined efforts to influence vaccine policy, Milne's zealous style of political lobbying antagonised the medical profession and aggravated existing tensions in his relationships with the Minister of Health and the Health Department.

During 1986, Alexander Milne and Chris Moyes continued to conduct hepatitis B prevalence surveys among school children in the North and East of the North Island. By early 1987, they had tested children in Kaeo, Whangarei, Thames, Coromandel, Paeroa, Whitianga and Rotorua.<sup>243</sup> While prevalence rates were variable, they were surprisingly high in some areas. In the Northland town of Kaeo, for example, they found that 43 per cent of high school children had blood test results that indicated past or present infection and that 7 per cent were hepatitis B carriers.<sup>244</sup>

On the basis of these sero-surveys, Milne and Moyes planned to persuade communities in Northland, Auckland, South Auckland, Rotorua, and Gisborne to fund low dose vaccination schemes for their preschool and young school children. At public meetings Milne argued strongly for preschool as well as infant hepatitis B immunisation in high

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<sup>242</sup> Department of Health Memorandum, 'Expanded hepatitis B immunisation programme', 28 October 1986, ABQU 632 W4452/697 131/171/1 61470, ANZW; Department of Health, Notes for speech by the Minister in opening the workshop for the expanded hepatitis B immunisation programme, 9 December 1986, ABQU 632 W4452/701 131/171/4 64435, ANZW.

<sup>243</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, pp.39-40.

<sup>244</sup> *ibid.* 'Hepatitis expert raps health board apathy', *Northern News*, 12 February 1987.

risk health districts. In press releases he ‘slammed’ the lack of urgency shown by the Northland Area Health Board in implementing an immunisation programme, declaring that ‘In a country where every third home has a video machine, most have cars and many smoke, I don’t accept that we can’t afford \$15 to protect our children against this, the most serious virus they are likely to meet.’<sup>245</sup>

Milne presented a challenge for public health officials. While he had produced groundbreaking research, and had been recognised internationally for his expertise on hepatitis B, he could be a vocal critic of government policy and a thorn in the side of local health authorities. In Northland, for example, he condemned the attitudes of health officials ‘who know the seriousness of the problem but either play it down or throw their hands up in the air because the cost of control is said to be too forbidding’.<sup>246</sup> Despite his sometimes abrasive relationship with the medical profession, however, Milne had undisputed experience of community-funded hepatitis B immunisation, and his public persona was closely linked with hepatitis B prevention.<sup>247</sup> In early December 1986, when the Health Department held a one day workshop to prepare public health staff for the implementation of the expanded immunisation programme, Milne was the only non-departmental speaker invited to attend.

Milne was characteristically outspoken during the workshop. In correspondence with Dr Keith Ridings, Medical Superintendent of Whakatane Hospital, Dr John Stoke, Manager of the Health Protection Programme, commented that Milne’s ‘down-to-earth, practical remarks are a great help to mental concentration and his advice ... was very closely listened to by all present with admiration, if not always total agreement!’ Stoke reassured Ridings that Milne’s regular use of the media to promote his cause was generally

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<sup>245</sup> *ibid.*

<sup>246</sup> *ibid.*

<sup>247</sup> In June 1986, Milne was made a member of the British Empire (MBE) for his services to the community in hepatitis B research. ‘MBE’; ‘Reward for research’, *NZH*, 14 June 1986; ‘Awards well deserved’, *Dominion*, 17 June 1986.

regarded in a positive light within the Health Department: ‘We accept here that his forays into the media, while frequently uncomfortable, act as a constructive provocation.’<sup>248</sup>

For his part, Milne was more than happy to provide advice on the best way to approach the new policy. In November 1986, he had written to the Health Minister Michael Bassett stating that ‘we know exactly what to do’. Among other pointers, Milne told Bassett that anything more than a low dose vaccine would be ‘wasteful’, and that ‘DOCTORS are not needed ... the cost of having them in the act will torpedo the whole scheme’.<sup>249</sup> The issue of cost, which was central to the hepatitis B debate, was problematic both for Bassett, who could not match the economies achieved by the community campaigners, and for Milne, who deplored what he saw as excessive use of funds by the state health system. When Ian McLean, Opposition MP for Tarawera, questioned Bassett over the difference between the total cost per head of the proposed Health Department vaccination programme and the community funded programme in the Bay of Plenty, Bassett responded that the Health Department scheme cost \$52.09 per head, compared with \$12-\$17 for the community campaign.<sup>250</sup>

In early 1987, in correspondence with David Lange, the Prime Minister, and Bassett, Milne kept up his campaign for low dose immunisation, slating government policies and Department of Health inaction while extolling the virtues of the Whakatane-based HRU: ‘The Department of Health is restricted by convention and protocol. We have knowledge, ability and drive.’<sup>251</sup> Milne’s style was relentlessly confrontational, and Bassett grew increasingly wary of the apparent contradictions between Milne’s cause and his character. As he later recalled, ‘Milne was really on to trying to help young kids, but he had a bee in his bonnet which would frequently escape from under the edge of his hat and sting people.’<sup>252</sup> Dr Michael Baker, Bassett’s medical secretary from 1986 to 1987, formed the impression that the Minister felt ‘bombarded’ by Milne. While Baker was aware of the

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<sup>248</sup> Stoke to Riding, 12 December 1986, ABQU 632 W4452/701 131/171/4 64435, ANZW.

<sup>249</sup> Milne to Minister of Health, 5 November 1986, ABQU 632 W4452/701 131/171/4 64435, ANZW.

<sup>250</sup> NZPD, 12 December 1986, ABQU 632 W4452/701 131/171/4 64435, ANZW.

<sup>251</sup> Milne to Prime Minister and Minister of Health, 7 January 1987, ABQU 632 W4452/706 131/171/4, ANZW.

<sup>252</sup> M. Bassett, interviewed by D. M. Jowitt, 26 April 2008.

important part played by health advocates in the policy making process, he later observed that ‘when you are on the receiving end in the Minister’s office ... it [can be] very annoying. It’s deliberately annoying of course ... to raise the profile of an issue’.<sup>253</sup>

Milne’s forthright promotion of community-driven immunisation also irritated GPs, some of whom were offended by his claims that they were only interested in hepatitis B immunisation if they could benefit themselves. One doctor, who chose to use the non de plume ‘A Local GP, Whakatane’, challenged Milne in the local newspaper: ‘I am paid a certain fee for administering the vaccine ... [but] ... I employ a nurse and secretary who spend time documenting, checking and contacting unvaccinated children at our own expense ... My motives are, I hope, unimpeachable’. He suggested that the Government was at fault rather than the doctors, ‘as they order \$1.2 billion worth of warships, but cannot afford the vaccine at one thousandth of the cost’.<sup>254</sup>

At the opposite end of the medical spectrum, Milne created disquiet among Health Department officials by discussing the provision of hepatitis B vaccine to Pacific countries under the umbrella of New Zealand’s newly expanded immunisation programme.<sup>255</sup> In early 1987, George Salmond, Director-General of Health, cautioned Milne against presuming he could represent the New Zealand government in such matters, ‘which should [only] be discussed by the health authorities of the countries concerned’.<sup>256</sup>

Throughout 1986 and early 1987, Milne took every opportunity to convince the Health Minister and the Health Department to introduce universal low dose childhood hepatitis B immunisation. While Milne’s detractors recognised he had a worthy cause, his relentless style of health advocacy, his disdain for doctors, and his outspoken criticism of health officials created antipathy and suspicion among the medical profession and the health bureaucracy.

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<sup>253</sup> M. Baker, interviewed by D. M. Jowitt, 30 August 2007.

<sup>254</sup> ‘Letter to the Editor: Vaccine: Motives of government queried’, *Whakatane Beacon*, 29 April 1987.

<sup>255</sup> Taylor to Milne, 15 December 1986; Milne to Tinielu, 27 January 1987, ABQU 632 W4452/706 131/171/4 75587, ANZW.

<sup>256</sup> DGH to Milne, 5 February 1987, ABQU 632 W4452/706 131/171/4 75587, ANZW.

### **Media influences on hepatitis B policy**

Public interest in hepatitis B, already piqued by Milne's activities, intensified after a television documentary in April 1987. In an election year, heightened community and media awareness of hepatitis B raised its political profile. As the election approached, the Health Minister Michael Bassett found himself under increasing pressure to meet public demands for a major expansion of the hepatitis B immunisation programme.

In early April 1987, the 'Close Up' Television New Zealand (TVNZ) documentary team contacted Dr Nigel Ashworth, Coordinator of the Health Department's Expanded Hepatitis B Immunisation Programme, to discuss its likely impact. The team also wrote to Bassett, requesting an interview. Bassett, who was at the Australian Health Minister's Conference in Perth, delayed his reply until 27 April 1987, three days before the programme went to air. Rather than air Bassett's reasons for his non-appearance (he had 'nothing to add' to the issue) the programme inferred that he was unwilling to face the cameras on the hepatitis B issue. According to Bassett, this distorted the facts. He made a formal complaint to TVNZ in early May 1987, in which he objected to the 'disgraceful conduct of [the] 'Close Up' team in relation to the programme ... the centrepiece of [which was] the shortcomings of the Government's Hepatitis B campaign'.<sup>257</sup>

Bassett had a point; the title, 'Hepatitis B: Needless Delay', captured the content of the documentary, which employed alarmist rhetoric and a 'cut and paste' approach to editing. The opening commentary set the tone:

If you are concerned about AIDS – and these days who isn't – then you should be just as concerned about hepatitis B. Caused by a virus ... similar to the AIDS virus, it's already rife in New Zealand and health authorities admit getting further out of control by the day.<sup>258</sup>

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<sup>257</sup> Minister of Health to Mounter, 5 May 1987, Bassett papers, 90-306-32, ATL.

<sup>258</sup> Newztel Log, 'Close Up', 'Hepatitis B: Needless delay', 30 April 1987, Bassett papers, 90-306-32.

The programme, which showcased the achievements of the Whakatane-based HRU, described Alexander Milne as ‘the tireless Scot’, whose important work preventing hepatitis B with low dose vaccine had been ‘blocked by bureaucracy’.<sup>259</sup> On screen, Milne demonstrated his mastery of the media by using everyday vernacular to present clear messages about the cost reductions offered by the use of low dose vaccine. The debate over the efficacy of the vaccine, a more complex issue for the general public to comprehend, received less attention. Dr Stewart Reid, Chairman of the CDCAC, explained its concerns over the use of doses lower than those recommended by vaccine manufacturers, and the need for a change in the Medicines Act before the Health Department could use the low dose option for a national immunisation programme. Spliced alongside Milne’s passionate health activism, however, Reid’s reasoned rationale for rejecting an apparent opportunity to protect all New Zealand children from hepatitis B had a hollow ring. Ashworth appeared equally constrained and ineffectual.<sup>260</sup>

‘Needless Delay’ had broad repercussions in the heightened public awareness and raised political profile of the hepatitis B problem. In his 1988 analysis of the ‘low dose decision’, John Martin, former Deputy-Director of Health (Administrative), drew attention to the skill with which Milne courted the media, in contrast to the apparent inability of the government ‘to get off the back foot’.<sup>261</sup> While Milne’s community-funded campaigns in the Eastern Bay of Plenty provided a human focus for the hepatitis B issue, the Health Department struggled to engage public interest in the complex technical issues involved in vaccine safety and the legalities of the Medicines Act.<sup>262</sup>

By Martin’s account, ‘Needless Delay’ was the catalyst for Bassett’s decision to resolve the hepatitis B immunisation issue before the coming election.<sup>263</sup> The documentary stirred the interest of opposition politicians who recognised an opportunity to expose

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<sup>259</sup> *ibid.*

<sup>260</sup> ‘Close Up’, ‘Hepatitis B: Needless delay’, 30 April 1987, P13464, TVNZ Archives, Wellington.

<sup>261</sup> J. Martin, ‘The Low Dose Decision’, 1988.

<sup>262</sup> J. Martin, personal communication, 23 November 2008.

<sup>263</sup> *ibid.*

government deficiencies during an election year.<sup>264</sup> It was well timed with regard to the political calendar; funding proposals for new programmes were due before Cabinet in June. Furthermore, decisive political action on the hepatitis B problem presented an opportunity for electoral support at a time of growing dissatisfaction with the Labour Government's economic policies. There was little doubt that the issue had gained political currency. In early May 1987, Bassett announced that the hepatitis B immunisation campaign was likely to be extended, while the National Party manifesto, which was launched in late July 1987, highlighted hepatitis B immunisation for preschool children as a post-election policy.<sup>265</sup>

Following Bassett's announcement, correspondence to the Minister of Health and the Health Department regarding hepatitis B immunisation increased.<sup>266</sup> Milne's community-funded campaigns, featured in 'Needless Delay', had set a precedent; if the government refused to act, concerned communities were prepared to consider local action. In a letter to Bassett in mid-June 1987, for example, members of the Panmure District School Committee, who represented families from a lower socio-economic suburb of East Auckland, wrote that some local parents were so concerned that they had arranged to have their children immunised by their family doctors. The cost for larger families was prohibitive, however, and they asked, 'Is there a subsidy available to us if we were to set up an immunisation programme ourselves?'<sup>267</sup>

Health professionals, too, were growing impatient for government action on hepatitis B immunisation. In late June 1987, Dr Anthony Cull, a senior paediatrician at Waikato

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<sup>264</sup> Bassett received several letters from government and opposition MPs in the lead up to the election, reflecting their constituents' concerns about hepatitis B immunisation. For example, Neilson to Bassett, 13 May 1987, Elder to Bassett, 3 June 1987; Lee to Bassett, 'Hepatitis B Immunisation', 18 June 1987. ABQU 632 W4452/697 131/71/4 62764, ANZW.

<sup>265</sup> Minister of Health, Press Release, 'Hepatitis immunisation campaign likely to be extended – Bassett', Bassett papers, 88-289-6, ATL; New Zealand National Party, 'Let's Get New Zealand Right: National Manifesto "87"', Wellington, 1987.

<sup>266</sup> Waiwharariki Branch, MWWL, to Minister of Health, 29 May 1987; Panmure District School Committee to Minister of Health, 15 June 1987; Mackie to Young, 24 June 1987; Bairds Intermediate School, Otara, to Minister of Health, 29 June 1987, ABQU 632 W4452/701 131/171/4 62751, ANZW.

<sup>267</sup> Panmure District School Committee, to Minister of Health, 15 June 1987, ABQU 632 W4452/701 131/171/4 62751.



Hospital, challenged the Health Department to rethink its hepatitis B policy. Cull had attended the Whakatane meeting in July 1986, and had subsequently written to Bassett in support of the use of low dose vaccine.<sup>268</sup> In mid-1987, in correspondence with Dr John Stephenson, Manager of the Department's newly formed Health Protection Programme, he wrote that 'Given the evidence we now have in New Zealand about hepatitis B carrier rates ... the outstanding priority is to immunise all Maori children, who are by far the most at-risk group'.<sup>269</sup> While Cull acknowledged there was controversy about low dose vaccination, he expressed a personal opinion that 'the Department has been ill-advised'. He urged reconsideration of the cost reductions offered by the low dose option: 'if we could accept low dose vaccination then problems of geographical distribution and race would no longer be significant'.<sup>270</sup>

In July 1987, communities in Gisborne and Northland brought their proposals for hepatitis B immunisation to Stephenson's attention. Dr Roger Hindle, a community paediatrician in Whangarei, wrote that 'every day general practitioners are being asked by concerned parents for advice'. Hindle, who had also attended the 1986 Whakatane meeting, referred to a request from Dr J. M. Brownlie, Medical Officer of Health for the Northland Area Health Board, to the Department's Medicines and Benefits Unit, asking if GPs could claim the immunisation benefit for each child given hepatitis B vaccine. The positive response from Wellington had galvanised local GPs; at a meeting of the Northland division of the New Zealand Medical Association, 76 per cent indicated their interest in providing free hepatitis B immunisation to children by this means.<sup>271</sup>

Hindle, an advocate for low dose vaccine, argued that even though the 'restraints inherent in the Medicines Act 1981 inhibit the low dosage option, there is no reason why

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<sup>268</sup> Cull told Bassett that he was 'dismayed to hear that your Advisory Committee has failed to endorse the recommendations made at the Whakatane meeting about low dose vaccination. I feel any reservations they have are academic, and ... not ... in the best interests of New Zealand children'. Cull to Minister of Health, 6 August 1986, ABQU 632 W4452/697 131/171/4 61470, ANZW.

<sup>269</sup> The Health Protection Programme was created during the 1986-87 organisational restructuring of the Department of Health. Its mission was to 'promote and protect the health of the public through the provision of advice and the monitoring and control of the physical, chemical and biological aspects of health', including communicable diseases such as AIDS and hepatitis B. AJHR, 1988, E.10, p.20.

<sup>270</sup> Cull to Stephenson, 25 June 1987, ABQU 632 W4452/701 131/171/4 62751, ANZW.

<sup>271</sup> Hindle to Stephenson, 14 July 1987, ABQU 632 W4452/701 131/171/4 62751, ANZW.

individual practitioners should not do so'. In his opinion there were benefits for both children at risk and for parents who were 'very seriously concerned about the whole Hepatitis B storm that has been "sweeping the media" for some time'. In his letter to Stephenson, Hindle hinted at the influence of political events on the development of health policy: '[I] hope to hear from you some time in the next few weeks (? before the election?)'.<sup>272</sup>

Television, then, proved to be a potent medium for political lobbying on the hepatitis B issue. Milne, who had already honed his campaign message in the print media and at numerous public meetings, was well-equipped to confront the cameras and to convince the public of the need for decisive action on hepatitis B immunisation. For Bassett, the screening of 'Needless Delay' represented a political tipping point on the hepatitis B issue.

### **Cabinet approval for low dose vaccine**

To cover the costs of an expanded hepatitis B immunisation programme, the Health Minister, Michael Bassett, had to gain Cabinet approval for additional funding. Bassett had little room to manoeuvre; the fiscal situation had improved, but there was still extreme pressure on discretionary expenditure. Under these circumstances, Bassett asked senior health officials to review the use of low dose hepatitis B vaccine.

In June 1987, at Bassett's request, John Stephenson, the Manager of the Health Protection Programme, reassessed the costs of mass childhood hepatitis B immunisation.

Stephenson presented Bassett with the departmental perspective: 'The only way to extend the existing programme, which is considered to be highly desirable, is by means of additional funds or by significant reduction of existing costs, or a combination of both.' Stephenson suggested that the use of low dose vaccine at one-fifth of the manufacturer's

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<sup>272</sup> *ibid.*

recommended dose presented an immediate solution to the challenge of financing an expansion of the immunisation programme.<sup>273</sup>

In his background paper, Stephenson indicated a reversal of the previous legal advice offered by Health Department officials. In his opinion, the use of low dose vaccine by the Department for an immunisation programme would not be ‘illegal’, rather ‘legal opinion concluded it would be legally unwise ... to consent to the distribution of a vaccine on the basis of a recommended dose and then alter that dose for the purpose of the Programme’. In this instance, he and senior Health Department officials considered the question to be one of risk which would be better dealt with by the Minister of Health and Cabinet than by a technical advisory body.<sup>274</sup>

On 18 June 1987, Bassett presented Cabinet with his initial request for funding for a low dose national immunisation programme. In terms of possible side-effects, the safety of hepatitis B vaccine was proven; however, there was still scant evidence of its long term efficacy if it was used in a low dose form. An attached memorandum focused on the Crown’s legal liability if Cabinet were to approve the low dose proposal. Mr J.G. B. Barnett, the Department’s solicitor, raised the prospect of the government being subject to claims of negligence by people who had been immunised, but who later contracted the disease as a result of receiving lower than the manufacturer’s recommended dose of hepatitis B vaccine. He advised that liability could be reduced by the use of carefully worded consent forms prior to immunisation.<sup>275</sup>

Over the ensuing weeks, Stephenson prepared the final Cabinet proposal. According to Kenneth Swann, the Acting Manager of the Medicines and Benefits section, the draft

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<sup>273</sup> Department of Health, Memorandum for the Minister of Health, ‘Further Expansion of Hepatitis B Immunisation Programme’, 9 June 1987, private papers, M. Bassett.

<sup>274</sup> In his 1988 paper, ‘The Low Dose Decision’, John Martin explained that this decision was based in part on the findings of the 1983 report of the Special Committee to investigate the Safety of Poliomyelitis Vaccine, chaired by Kenneth Newell, which concluded that ‘no ... technical group of advisers has any unique qualifications which gives them the right to make social judgments as to what is “safe” and “unsafe”’.

<sup>275</sup> Minister of Health, Memorandum for Cabinet, ‘National Hepatitis B Immunisation Programme’, 18 June 1987, ABQU 632 W4452/702 131/171/4 62752, ANZW.

document was not widely circulated before going to the Minister. Swann wrote to Martin and Stephenson to put his views on record. He had serious reservations about two aspects of the proposed programme: the savings anticipated from a change to the Immunisation Benefit paid to general practitioners and the legal issues involved in implementing a low dose hepatitis B immunisation programme.<sup>276</sup>

Swann was not the only one with cause for concern; members of the CDCAC were disturbed to discover that announcements had been made by both Milne and the Health Department on plans to expand the hepatitis B immunisation campaign, and that the Government was considering a low dose programme.<sup>277</sup> On 20 July 1987, Rod Ellis-Pegler telephoned the Department to express disquiet that neither he, nor the other members of the CDCAC Hepatitis B Subcommittee had been consulted on the low dose proposal. He explained that Stewart Reid, Chairman of the CDCAC, had no knowledge of the proposed plans either.<sup>278</sup>

Bassett and Stephenson were in Sydney, attending an Asian-Pacific AIDS summit called by the WHO to coordinate an 'all-out attack' on the disease.<sup>279</sup> When contacted, Stephenson confirmed that the CDCAC had not been formally consulted on the low dose proposal. George Salmond, the Director-General of Health, and John Martin, his senior administrator, conferred; on his return, Bassett was to be provided with all relevant records of previous meetings where the low dose option was discussed. The next CDCAC meeting was planned for 20 August 1987, and the low dose issue would be on the agenda.<sup>280</sup>

The final paper presented to Cabinet on 27 July 1987 proposed an ongoing immunisation programme for newborn babies, close household and sexual contacts of carriers, and a

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<sup>276</sup> Swann to Martin and Stephenson, 'National Hepatitis B Immunisation Programme', 29 June 1987, ABQU 632 W4452/702 131/171/4 62752, ANZW.

<sup>277</sup> 'Campaigner tips hepatitis moves', *Sunday Times*, 19 July 1987; 'Child vaccine campaign being widened', EP, 20 July 1987.

<sup>278</sup> Patel and Handford to Martin, 21 July 1987, ABQU 632 W4452/701 131/171/4 62751, ANZW.

<sup>279</sup> Minister of Health, News Release, 'Minister releases details of AIDS Awareness Week before departing to AIDS summit', 19 July 1987, Bassett papers, 88-289-61.

<sup>280</sup> Patel and Handford to Martin, 21 July 1987, ABQU 632 W4452/701 131/171/4 62751, ANZW.

once-off ‘catch-up’ programme for preschoolers using low dose vaccine. An accompanying legal opinion circumvented Swann’s concerns. According to Barnett, Section 24 of the Medicines Act did not prevent the Health Department from using lower than the manufacturer’s recommended dose of vaccine. He maintained the view that ‘a consent to distribute [a new medicine] at a recommended dosage’ could not be considered a ‘mandatory, statutory requirement on persons who administer the medicine(s) that only the recommended dosage is to be used’.<sup>281</sup>

On 29 July 1987, Swann and his senior medical colleagues in the Medicines and Benefits Unit, Dr R.C. Riseley and Dr Susan Martindale, made a last ditch effort to dissuade the Health Department from supporting the low dose decision. In a memo to Salmond, Swann stated that the use of low dose vaccine in the national immunisation programme would place the Medicines and Benefits Unit in an invidious position: ‘Unless [the Department] is explicit that this was a Government decision, [we] will be in an untenable position in requiring companies to provide information ... if ...we [are seen to] ignore the legislation when it suits’.<sup>282</sup>

Cabinet approval for the low dose immunisation programme was publicly announced on 30 July 1987, at the pre-election launch of the Labour Government’s health policy. Funding of \$4.17 million was made available over three years to support the scheme.<sup>283</sup> With the election only two weeks away, a positive wave of correspondence to Bassett on the hepatitis B issue indicated the government had made a timely political decision. Groups as diverse as the Young Women’s Christian Association, the Women’s Division of Federated Farmers and the Children’s Health Camps Board wrote to congratulate the Minister and the Health Department on the proposed immunisation campaign.<sup>284</sup>

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<sup>281</sup> Barnett to Martin, ‘Hepatitis B Immunisation Programme’, 23 July 1987, ABQU 632 W4452/702 131/171/4 62752, ANZW.

<sup>282</sup> Swann to DGH, ‘Hepatitis B Vaccine’, 29 July 1987, ABQU 632 W4452/702 131/171/4 62752, ANZW.

<sup>283</sup> Minister of Health, News Release, ‘Bassett on Expanded Hepatitis B Immunisation Programme’, 30 July 1987, ABQU 632 W4452/702 131/171/4 62752, ANZW.

<sup>284</sup> YWCA to Minister of Health, 23 July 1987; WDFP to Minister of Health, 31 July 1987; Avondale Health Centre to Minister of Health; Children’s Health Camp Board to DGH, 4 August 1987, ABQU 632 W4452/701 131/171/4 62751, ANZW.

At the August meeting of the CDCAC, the Health Department formally requested further consideration of the low dose proposal. Milne was invited to present the unpublished results of a study of over 1,000 children which confirmed the efficacy of the low dose approach, and in addition, suggested that four doses of low dose vaccine were comparable to, or better, than the manufacturer's recommended three dose course of full strength vaccine.<sup>285</sup> The CDCAC agreed that the new data provided 'sufficient evidence to proceed with further expansion of the hepatitis B immunisation programme using lower than the manufacturer's recommended doses'. Nevertheless, despite their support for the use of low dose vaccine, committee members expressed doubts about the ease with which the public health system could mount a nationwide preschool immunisation campaign. Their own preference was for immunisation at school entry when children could be easily identified and followed up over a lengthy course of vaccine.<sup>286</sup>

Before moving on to other agenda items, the committee added a wry reminder to the Minister or the Department of Health; if they needed advice on implementing the national immunisation programme, the CDCAC Hepatitis B Subcommittee should be consulted.<sup>287</sup> The combined technical expertise and clinical experience of its members was a significant resource, and one which should not be ignored in the policy making process.

## **Conclusion**

During 1986, following Dr Eru Pomare's endorsement of hepatitis B as a serious public health problem, the Health Minister Michael Bassett came under increasing pressure to fund a more extensive hepatitis B immunisation programme. Persistent lobbying by Alexander Milne, high profile visits by international experts in viral hepatitis, the apparent potential for a delta virus epidemic, extensive media coverage and the growing public and political attention to the hepatitis B problem, all pushed hepatitis B up the health policy agenda.

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<sup>285</sup> CDCAC minutes, 20-21 July 1985, Ministry of Health Archives, Wellington.

<sup>286</sup> *ibid.*

<sup>287</sup> *ibid.*

Milne, who epitomised the health zealot, attracted the attention of the local and national media, who supported his efforts to introduce low dose childhood hepatitis B immunisation.<sup>288</sup> His passionate promotion of low cost, community based immunisation alienated some members of the medical profession, but his no-nonsense, direct approach had an inherent appeal for the general public who had little concept of the funding and legal constraints on policy making. To advance his views, Milne utilised Whakatane as an alternative venue for policy discussion. Through his personal connections in the international hepatitis research network he exerted a powerful influence on policy makers from outside of the health establishment.

Bassett, who had limited resources for public health, claimed that the high price of the full dose hepatitis B vaccine presented an insurmountable obstacle to nationwide childhood immunisation. As public expectations of government action on the hepatitis B problem grew, Bassett looked to the low dose vaccine as a solution to his funding shortfall. When he expressed an intention to use low dose vaccine in the state-funded immunisation programme, however, he met with opposition from within the Health Department, and from the CDCAC, the official advisory body on immunisation matters. While the CDCAC advocated a more expansive hepatitis B immunisation policy, it maintained that the manufacturer's recommended dose should be used for the national immunisation programme. In the event, the CDCAC's inability to reach a consensus on the use of the low dose vaccine reduced its influence on the policy making process. Bassett and senior Health Department officials alternately consulted the CDCAC and overrode its advice on the low dose option.

Political pressures, rather than technical advice, provided the push to announce the expansion of the hepatitis B immunisation programme just prior to the general election. With the backing of Cabinet, New Zealand became the first country in the world to plan a

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<sup>288</sup> As John Martin explained in his paper 'The Low-dose Decision', 'the term "zealot" had a non-judgmental meaning in public administration literature ... [it referred to] a person focused on a defined policy goal and dedicated to its achievement', p.6.

mass immunisation programme using low dose hepatitis B vaccine.<sup>289</sup> The decision to expand state-funded immunisation met public expectations for a more comprehensive hepatitis B control strategy, nevertheless, as the next chapter will discuss, the implementation of the new policy would prove more challenging than either Bassett or the Health Department could have foreseen.

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<sup>289</sup> The Health Department later described the expanded programme as ‘the most extensive in the world and unique in its use of low-dose immunisation on this scale’. AJHR, 1988, E.10, p.17.



## **CHAPTER SIX**

### **THE EXPANSION OF THE HEPATITIS B IMMUNISATION PROGRAMME**

**1987–1989**

This chapter will begin by discussing the deliberations over the final shape of the expanded hepatitis B immunisation programme which embraced infants and preschool children, and which Health Minister Michael Bassett had promised to introduce following the 1987 election. The response of senior health officials and community health advocates to this initiative will be addressed. The chapter will then discuss the difficulties that arose during the preschool campaign. In particular, the problems relating to the vaccine uptake among Maori children will be considered in the light of the Health Department's commitment to a bicultural approach to the planning and implementation of health policies. Finally, the chapter will examine the political response to increasing pressure to expand the immunisation programme to all school-aged children, and will trace the beginnings of the major policy conflict that was to dominate the 1990s, the identification and follow up of hepatitis B carriers.

#### **The introduction of the expanded immunisation programme**

At the launch of Labour's Health Policy in the run up to the 1987 general election, Health Minister Michael Bassett announced a major expansion of the hepatitis B immunisation programme. The finer details of the new programme were still undecided; nonetheless, Bassett was confident that the expansion of state-funded immunisation to all newborn babies and preschool children would meet public demands for a more comprehensive hepatitis B policy. Despite a victory at the polls, however, his hopes of delivering on his election pledge were dashed by unexpected changes within the Labour Cabinet.

On 19 August 1987, four days after winning a second term, Prime Minister David Lange instigated a major Cabinet reshuffle. In the new line-up, David Caygill, previously

Minister of Trade and Industry, replaced Bassett as Minister of Health. In his memoirs of the Fourth Labour Government, Bassett described the loss of Health as a bitter blow, like the ‘unexpected death of a dearly-loved invalid relative’. He was deeply reluctant to relinquish the role: ‘after three years in the job I’d learned what to do with a portfolio that had had so many changes of ministers over the years there’d been little policy continuity’.<sup>1</sup> Bassett maintained that Caygill was equally unwilling to accept his new responsibilities, protesting to Lange that ‘it would take him a year to come up to speed’.<sup>2</sup>

Caygill, who had limited knowledge of health issues, postponed policy decisions while he familiarised himself with his new role.<sup>3</sup> During this adjustment phase, officials briefed him on policy matters, including the expansion of the hepatitis B immunisation programme. Discussions focused on funding, the proposal to target preschool rather than school-aged children, and the vexing question of which vaccine to use.

Plasma-derived hepatitis B vaccine, produced from the blood of healthy hepatitis B carriers, had been used in New Zealand since 1982. In 1986, a genetically-engineered recombinant hepatitis B vaccine had been developed in the US, and by August 1987, it was close to registration in New Zealand.<sup>4</sup> The new vaccine was made by inserting the gene for hepatitis B antigen into baker’s yeast, which was then cultured in large fermentation tanks, releasing copious quantities of hepatitis B antigen for purification. Recombinant vaccine offered important advantages; it was cheaper to produce, and it removed the theoretical risk of transmitting the human immunodeficiency virus (HIV) through hepatitis B immunisation.

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<sup>1</sup> M. Bassett, *Working with David: Inside the Lange Cabinet*, p.276.

<sup>2</sup> Caygill was Minister of Trade and Industry from 1984 to 1987, and Minister of Finance from 1989 to 1990. *ibid.*, p.281.

<sup>3</sup> In October 1987, Mike Munro, parliamentary correspondent for the *New Zealand Medical Journal*, noted the ‘gentle measured beginning by the new health minister’, and his ‘generous settling in period’. M. Munro, ‘Politics and Health: Way Ahead’, *NZMJ*, 28 October 1987, p.670.

<sup>4</sup> ‘US approves hepatitis B genetic vaccine’, *Dominion*, 25 July 1986; Anon., ‘New recombinant DNA Hep B vaccine’, *Communicable Disease New Zealand (CDNZ)*, 87/9, September 1987, pp.16-8.

In the US, UK, Europe, Australia and New Zealand, plasma-derived hepatitis B vaccine had been dogged by persistent reports that it was contaminated with HIV.<sup>5</sup> Homosexual men, at the centre of the Acquired Immune Deficiency Syndrome (AIDS) epidemic in the US, were known to have provided hepatitis B-positive plasma for the production of the first hepatitis B vaccine.<sup>6</sup> The rumoured association between AIDS and hepatitis B vaccine had been disproved after the discovery of HIV in late 1984.<sup>7</sup> Nevertheless, many people, including doctors, remained suspicious of a vaccine made from human blood.<sup>8</sup>

In New Zealand, public perceptions of vaccine safety had become increasingly important to the Health Department in the aftermath of the meningococcal immunisation campaign in Auckland in May and June 1987.<sup>9</sup> The Department's paternalistic handling of parental concerns about the side-effects of the meningococcal vaccine had caused an intense burst of negative media publicity. In her PhD thesis, Alison Day explained the meningococcal campaign was the first time health officials had encountered such strong media criticism and parental resistance to immunisation. Day argued that the campaign had a profound effect on the planning and delivery of future programmes: 'this controversy was a turning point for the Department in the way it perceived its relationship with parents in terms of immunisation'.<sup>10</sup>

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<sup>5</sup> See for example, W. Muraskin, 'The Silent Epidemic: The Social, Ethical and Medical Problems Surrounding the Fight Against Hepatitis B', p.285; J. M. Stanton, 'What shapes vaccine policy? The case of hepatitis B in the UK', pp.432-3; R. Walgate, 'Hepatitis B: Pasteur in AIDS fracas', *Nature*, 304, 5922, 14 July 1983, p.104, EAC minutes, 13 October 1983, AAFB 786 W3045/8. In New Zealand in the early 1980s, although most health care workers actively sought hepatitis B immunisation, some doctors regarded the vaccine as a potential source of HIV. Anonymous source.

<sup>6</sup> W. Szmunes, C. E. Stevens, E. J. Harley, E. A. Zang, W. R. Oleszko, D. C. William, R. Sadovsky, J. M. Morrison, and A. Kellner, 'Hepatitis B Vaccine: Demonstration of efficacy in a controlled clinical trial in a high-risk population in the United States', *NEJM*, 303, 15, 9 October 1980, pp.833-41.

<sup>7</sup> CDC, 'Hepatitis B vaccine: evidence confirming lack of AIDS transmission', *MMWR*, 33, 14 December 1984, pp.685-7.

<sup>8</sup> Scientist Maurice Hilleman, who developed the blood-derived hepatitis B vaccine for MSD, claimed that when the vaccine first came on the market 'We had one hell of a time. The doctors and nurses didn't want to be vaccinated with human blood.' P. A. Offit, *Vaccinated: One Man's Quest to Defeat the World's Deadliest Diseases*, p.136.

<sup>9</sup> F. MacDonald, 'Meningitis: Campaign goes astray', pp.16-8.

<sup>10</sup> A. S. Day, 'Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920 – 1990', pp.259-60.

The adverse experience of the meningococcal vaccination campaign undoubtedly influenced official advice given on the hepatitis B immunisation programme. In June and July 1987, Dr John Stephenson, Manager of the Health Protection Programme, had prepared briefing papers for Bassett on an extension to the hepatitis B immunisation programme. In these papers, Stephenson had explicitly stated that the savings that could be achieved through the use of low dose vaccine would enable a nationwide preschool campaign, and that this option presented a number of crucial advantages.<sup>11</sup> Six weeks later on 28 August 1987, however, in a report to Dr George Salmond, the Director-General of Health, Stephenson had changed tack completely. He cited the loss of public credibility during the meningococcal vaccination campaign:

The Government has been widely criticised in its use of meningococcal vaccine in Auckland ... further attacks will be mounted if the Government and Department are perceived as saving money by questionable methods ... use of lower doses [of vaccine] than recommended by manufacturers is unwise ... [because] of public trust and acceptance.<sup>12</sup>

Stephenson contended that recombinant vaccine would be preferable to a vaccine which was produced from the blood of hepatitis B carriers, noting that Merck Sharpe and Dohme (MSD), the US vaccine company, 'propose[d] to advertise that recombinant vaccine is the better product [because] it cannot transmit AIDS'.<sup>13</sup> The choice of vaccine was also important from an operational perspective. While full strength recombinant vaccine was administered in three doses over six months, four doses of low dose plasma-derived vaccine were required over twelve months. Stephenson argued that there would be logistical problems in ensuring the completion of the four dose course of low dose vaccine especially among 'the group at most risk who tend to be a mobile and sometimes socially deprived community with limited access to primary health care'.<sup>14</sup>

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<sup>11</sup> Memorandum for the Minister of Health, 'Further Expansion of Hepatitis B Immunisation Programme', 9 June 1987, Health Department, Wellington, private papers, M. Bassett.

<sup>12</sup> Stephenson to DGH, 28 August 1987, ABQU 632 W4452/701 131/171/4 62751, ANZW.

<sup>13</sup> *ibid.*

<sup>14</sup> *ibid.*

Stephenson had been a medical officer of health in Auckland before joining the head office of the Health Department in the mid-1980s. This role had exposed him to the realities of implementing departmental policies at the coalface of public health. Dr Arvind Patel, Assistant Director of the Communicable Diseases Unit in the Health Protection Programme, regarded Stephenson as more sympathetic to local than national concerns: ‘He was still focused on helping people ... not so much on [funding] or the politics [of public health]’.<sup>15</sup>

Stephenson sought a compromise between evidence-based research and the limited resources available to existing services. If infected with the hepatitis B virus, preschool children were much more likely than older children to become chronic hepatitis B carriers and to act as an ongoing source of infection for other children. However, school children could be located with minimal effort, while preschool children had fewer formal links to the health system. As Day observed, ‘[Preschool children] were particularly difficult to access because parental cooperation was required’.<sup>16</sup> Stephenson warned that public health nurses carrying out the preschool programme as well as their routine work would be unlikely to duplicate the high immunisation rates achieved by Alexander Milne’s Whakatane-based Hepatitis Research Unit (HRU) among preschoolers during community immunisation campaigns.<sup>17</sup>

At a local level, the Health Department expected public health workers to implement and promote immunisation policies alongside their other duties. During the initial expansion of the hepatitis B immunisation programme in early 1987, for example, Dr Dwayne Crombie, a community medicine registrar in South Auckland, reported that ‘No new resources were made available ... apart from the cost of the vaccine and its supply and some health education pamphlets’. In Crombie’s experience, district offices were simply

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<sup>15</sup> A. Patel, interviewed by D. M. Jowitt, 16 August 2008.

<sup>16</sup> A. S. Day, ‘Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920–1990’, p.188.

<sup>17</sup> Stephenson to DGH, 28 August 1987, ABQU 632 W4452/701 131/171// 62751. Milne relied on voluntary workers to assist with the community-funded immunisation programmes.

expected 'to prioritise their time and redirect their work and energy accordingly'.<sup>18</sup> Under these conditions, short-term projects were clearly preferable to prolonged campaigns.

Stephenson's advice on preschool immunisation was consistent with that offered by the CDCAC.<sup>19</sup> The committee recommended that before the final decision was made on the low dose immunisation campaign, the resources available to the public health system should be carefully considered, because 'the immunisation programme in the Eastern Bay of Plenty relied strongly on community funding and voluntary participants'. The CDCAC recognised the value of opportunistic immunisation clinics for preschoolers in areas of high hepatitis B prevalence, but it did not advocate a national preschool immunisation campaign.<sup>20</sup>

In its advice to medical practitioners in February 1988, before the start of the preschool campaign, the Hepatitis Subcommittee of the CDCAC explained that its preference had been to target children at entry to primary and intermediate school, 'on the basis that it would be more easy to deliver such a programme to children in schools than to pre-school children'.<sup>21</sup> The professional experience of CDCAC members, some of whom were in general practice and paediatric specialties, convinced them that a school-based approach would result in higher immunisation rates overall.<sup>22</sup> The CDCAC had recommended to the Minister of Health that if the Health Department offered hepatitis B immunisation at birth and on entry to primary and intermediate school, all children up to the age of sixteen could be immunised over a five year period.<sup>23</sup> Nevertheless, this

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<sup>18</sup> D. Crombie, 'Expanded Programme 1987: Hepatitis B Programme Implementation', South Auckland District Health Office, 1987, private papers, D. Crombie.

<sup>19</sup> Dr Arvind Patel, Assistant Director (Communicable Diseases), medical secretary of the CDCAC, reported directly to Stephenson, who was privy to the minutes and recommendations of the committee.

<sup>20</sup> CDCAC minutes, 20-21 August 1987, Ministry of Health Archives, Wellington.

<sup>21</sup> Circular Letter to Medical Practitioners 1/88, 'Department of Health New Hepatitis B Immunisation Programme', 19 February 1988, ABQU 632 W4452/702 131/17/4 64448, ANZW.

<sup>22</sup> Several members of the CDCAC had published on immunisation issues, including Stewart Reid, Diana Lennon, John Clements and Arvind Patel. See, for example, J. S. Reid, H. J. Graham-Smith, 'Childhood immunisations: a recall system is worthwhile', NZMJ, 97, 1984, pp.688-9; I. R. B. Hardy, D. R. Lennon, E. A. Mitchell, 'Measles epidemic in Auckland 1984-85', NZMJ, 100, 13 May 1987, pp.273-5; M. Tobias, J. Scadden, J. Clements, A. C. Patel, 'Measles immunity in children: the 1985 national immunisation survey', NZMJ, 100, 27 May 1987, pp.315-7.

<sup>23</sup> CDCAC minutes, 20-21 August 1987.

proposal did not meet with ministerial approval as it involved what were considered unacceptably high levels of funding.

From Caygill's perspective, funding presented a major obstacle to a school-based programme. MSD had reduced the retail price of both the plasma-derived and recombinant vaccines by 60 per cent for the bulk purchase by the Health Department, but the CDCAC had no scientific data on the efficacy of recombinant vaccine in low doses.<sup>24</sup> The original funding proposal had been based on low dose plasma-derived vaccine, a birth rate of 52,000 per year, and an estimated preschool population of 220,000. A large budget overrun was inevitable if the Health Department implemented a scheme that would involve over 500,000 school-aged children and the use of full dose recombinant vaccine.

On 7 October 1987, Caygill announced the final details of the expanded immunisation programme. A low dose of 'the present vaccine' was to be offered to all babies and preschool children, while full dose plasma-derived vaccine would be used for the babies of carrier mothers, 'where the risk of infection is considered to be high'.<sup>25</sup> Despite official advice that preschoolers would prove difficult to reach, that a longer campaign would reduce immunisation coverage, and that there would be problems convincing the public of the safety of the blood-based vaccine, financial priorities prevailed. For Caygill, cost remained the overriding consideration in the final shape of the infant and preschool hepatitis B immunisation programme.

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<sup>24</sup> *ibid.* Even at Merck Sharpe and Dohme's bulk purchase price, \$11.84 per child dose, using full dose recombinant vaccine for the newborn and preschool programme would cost approximately \$17 million over three years. This was more than four times Stephenson's original calculation of \$4.1 million for the use of low dose plasma-derived vaccine. Stephenson to DGH, 28 August 1987, ABQU 632 W4452/701 131/171/4 62751; Merck Sharpe and Dohme, 'Submission Document to the Department of Health on the New Zealand Child Vaccination Programme for Hepatitis B', 18 August 1987, ABQU 632 W4452/702 131/171/4 62752, ANZW.

<sup>25</sup> , Minister of Health, News Release, 'The hepatitis B immunisation programme is to be expanded', 7 October 1987, ABQU 632 W4452/702 131/171/4 62752, ANZW.

### **Pressure to start the preschool programme**

Alexander Milne claimed David Caygill's decision to introduce low dose infant and preschool immunisation as a victory for the campaign waged by the Whakatane-based HRU, and for the 'strong consistent support from New Zealand newspapers from Kaikohe to Wellington'.<sup>26</sup> While he described the preschool campaign as an 'innovative programme used nowhere else in the world', he took issue with the measured pace at which it was being implemented, and the limited extent of the hepatitis B policy.<sup>27</sup>

From early September 1987, Milne lobbied the new Health Minister to make an immediate start on the expanded programme of immunisation. Milne had recently returned from a World Health Organization (WHO) meeting on hepatitis B prevention in Seoul, where he had acted as an international advisor.<sup>28</sup> Citing the WHO report as an endorsement of the use of low dose vaccine as an 'appropriate strategy' in the New Zealand situation, Milne urged Caygill to expedite the introduction of the programme:

I would stress the urgency that we should get on with the job, cutting all corners which obstruct progress. Every month of delay means a large number of children will become infected, and many will remain carriers for life. All high risk children should have had their third dose of vaccine by Christmas 1987.<sup>29</sup>

Milne had extensive experience in organising community-funded immunisation programmes; however, he appeared to have little sense of the challenges of implementing a nationwide vaccine programme. While John Stephenson and the CDCAC were daunted by the prospect of delivering a lengthy low dose regimen to preschool children, Milne blithely advised the Minister that it would be 'quite convenient to recall New Zealand children for a fourth dose' of vaccine. Moreover, Milne suggested that the Health

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<sup>26</sup> Milne had established the HRU on the Whakatane Hospital premises in 1986, to coordinate local hepatitis B research and to provide a means of following up hepatitis B carriers identified during the Kawerau and subsequent studies. V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, pp.39-42.

<sup>27</sup> Milne to Minister of Health, 28 January 1988, ABQU 632 W4452/703 131/1714 65315, ANZW.

<sup>28</sup> WHO, Regional Office for the Western Pacific, 'Meeting of the Working Group on Hepatitis B', Seoul, Korea, 24-26 August 1987, ABQU 632 W4452/702 131/171/4 62752, ANZW.

<sup>29</sup> Milne to Minister of Health, 2 September 1987, ABQU 632 W4452/702 131/171/4 62752, ANZW.



Department should be planning prevalence studies among school children in high risk health districts, as ‘all should realise that as soon as we begin vaccinating preschoolers, parents will demand protection for their 5, 6, 7, 8 year olds’.<sup>30</sup> Both Milne and his medical colleague, Chris Moyes, believed that the high levels of participation they had achieved in locally-driven immunisation projects could easily be replicated on a national scale.

Milne and Moyes spoke from an authoritative position; not only was Milne regularly invited to attend WHO meetings on hepatitis B control, but by the mid-1980s, they had co-authored at least seven scientific papers on hepatitis B immunisation in childhood, four of which had been published by international journals such as the *Lancet* and *Journal of Medical Virology*.<sup>31</sup> Moreover, in mid-1986, Milne had negotiated half-time salary support from the Medical Research Council (MRC) to undertake hepatitis B studies from Whakatane.<sup>32</sup> Notwithstanding the tensions that had arisen as a result of Milne’s vocal criticism of government policy, the Health Department acknowledged his and Moyes’ in-depth experience and research capability. The Department had endorsed their publication *Hepatitis B: A Guide for Health Professionals in New Zealand*, and in early October 1987, Dr Nigel Ashworth, National Coordinator of the Hepatitis B Immunisation Programme, invited both men to join the working party established to advise on the implementation of the preschool programme.<sup>33</sup>

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<sup>30</sup> Milne to Minister of Health, 2 September 1987, ABQU 632 W4452/702 131/171/4 62752.

<sup>31</sup> See for example: C. D. Moyes, A. Milne, M. Dimitrakakis, P. N. Goldwater, N. E. Pearce, ‘Very-low-dose hepatitis B vaccine in newborn infants: an economic option for control in endemic areas’, *Lancet*, 329, 8523, 3 January 1987, pp.29-30; A. Milne, M. Dimitrakakis, C. Campbell, C. R. Lucas, G. K. Allwood, P. N. Goldwater, N.E. Pearce, S. Krugman, ‘Low-dose vaccination against hepatitis B in children: One-year follow-up’, *Journal of Medical Virology*, 22, 1987, pp.387-92; A. Milne, M. Dimitrakakis, G. K. Allwood, C. R. Lucas, C.D. Moyes, N. E. Pearce, ‘Immunogenicity of low doses of hepatitis B vaccine in children: A study in 650 New Zealand children’, *Journal of Medical Virology*, 23, 1987, pp.401-5; A. Milne, G.K. Allwood, C.D. Moyes, N.E. Pearce, K. Newell, ‘A seroepidemiological study of the prevalence of hepatitis B infections in a hyperendemic New Zealand community’, *International Journal of Epidemiology*, 16, 1, 1987, pp.84-90.

<sup>32</sup> Milne to Hodge, MRC, 26 June 1986; Hodge to Milne, 30 June 1986; Milne to MRC, 23 September 1986, YCBN 5990 18b 11/6/11b, ANZA.

<sup>33</sup> C. D. Moyes and A. Milne, *Hepatitis B Infection: A Guide for Health Professionals in New Zealand*, Hepatitis Research Unit, Whakatane, 1987; ‘Mr Milne will be consultant’, *Whakatane Beacon*, 9 October 1987; Department of Health, Circular Memorandum, Ashworth to AHBs, ‘Expanded Hepatitis B Immunisation Programme (1988)’, 22 October 1987, ABQU 632 W4452/703 131/1714 62752, ANZW.

Ashworth, who took ‘an instant liking to Sandy because he called a spade a spade’, considered Milne and Moyes ‘central figures on the working party’.<sup>34</sup> For his part, Milne, who was more than willing to advise public health officials on the implementation of the preschool programme, had little patience for the hierarchical nature of the health bureaucracy. He took pride in the efficiencies he had achieved in community-funded immunisation campaigns, and he objected strongly to the convoluted discussions and lengthy negotiations required to implement national vaccine policy. During planning for the preschool campaign, for example, after attempting to reach Caygill by phone, he wrote to Stephenson to advise him to ‘overhaul Health Department management processes’. Milne, who stated a preference for ‘simple, prompt decisions’, complained bitterly at the delays caused by the ‘unnecessarily complex lines of communication’ between health bureaucrats in Wellington and public health workers in the regions.<sup>35</sup>

In Milne’s experience, the most effective way of delivering hepatitis B immunisation was by lobbying to gain community support for local programmes using voluntary labour and low dose vaccine. While he was willing to work with the Health Department to introduce a more comprehensive hepatitis B programme, he preferred more direct methods of health advocacy. As Chapter Four and Five discussed, during the early and mid-1980s, Milne had become renowned for his single-minded pursuit of state-funded hepatitis B immunisation for children, and for attracting the interest of international experts in the New Zealand situation. Milne himself described this as a deliberate strategy to ‘establish [his] credibility’ and to highlight the serious nature of the hepatitis B problem.<sup>36</sup>

In October 1987, Milne volunteered to organise a South Pacific Commission (SPC) conference on hepatitis B, re-located from Fiji to Whakatane as a result of a military takeover. Link Consultants, which provided public relations advice to government departments, regarded the conference as a ‘notable coup’ for Milne, ‘at a time when Hepatitis B is such a major issue here’.<sup>37</sup> From a public relations perspective, Link was

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<sup>34</sup> N. Ashworth, interviewed by D. M. Jowitt, 8 February 2007.

<sup>35</sup> Milne to Stephenson, 17 December 1987, ABQU 632 W4452/701 131/171/4 62751, ANZW.

<sup>36</sup> L. Guerin, ‘Undercover epidemic’, p.18.

<sup>37</sup> Link Consultants was situated in the ‘Beehive Wing’ of Bowen House, Wellington.

certain that there would be considerable media interest in the SPC meeting: 'The range of speakers, the topicality of the subject matter and the very fact that an international conference is being held in Whakatane will mean that it is news.'<sup>38</sup>

As predicted, the SPC conference, held in mid-November 1987, received widespread media coverage and official attention.<sup>39</sup> Sir Paul Reeves, the Governor-General, made a special detour from his vice-regal duties to appear briefly in support of hepatitis B prevention.<sup>40</sup> The guest speakers included Professor Saul Krugman from the New York University School of Medicine, and Dr John Maynard, Head of the Hepatitis Division at the Centers for Disease Control (CDC), both of whom had already been involved in the New Zealand immunisation debate. Others, like Dr Brian McMahon from the Alaska Area Native Medical Centre, were new to the country but familiar with the problem of endemic hepatitis B in indigenous populations.<sup>41</sup>

The three day conference, which focused on hepatitis B immunisation for children in areas of high hepatitis B prevalence, endorsed the New Zealand low dose programme as an affordable alternative to full dose vaccine. Participants of the conference recommended that in high risk areas of the world, priority should be given to mass hepatitis B immunisation programmes for newborn babies, and that once these were established, consideration should be given to the immunisation of children to 'at least the age of five'.<sup>42</sup>

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<sup>38</sup> Martin to Ashworth, 'Hepatitis B campaign', 27 October 1987, ABQU 632 W4452/706 131/1714 75586, ANZW.

<sup>39</sup> 'Fijian turmoil shifts medical venue', NZH, 4 October 1987; 'Whakatane will host world's hepatitis experts', *Whakatane Beacon*, 6 October 1987; 'Sir Paul for conference', *Whakatane Beacon*, 6 October 1987; 'Aid urged for Pacific poor', NZH, 15 November 1987; 'Hepatitis B big killer but unseen', NZH, 16 November 1987; 'Mass vaccination plan for Pacific babies', *Auckland Star*, 16 November 1987; 'Hepatitis B conference ends on a high note', *Whakatane Beacon*, 18 November 1987.

<sup>40</sup> 'Sir Paul for conference', *Whakatane Beacon*, 6 October 1987. Reeves, whose Maori ancestry may have contributed to his support for hepatitis B prevention, later became a patron of the Hepatitis Foundation, established by Milne in 1992 to promote hepatitis B research and the follow up of hepatitis B carriers.

<sup>41</sup> South Pacific Commission Scientific Meeting, 'Control of Hepatitis B Infections in Infants and Children in High Risk Areas of the World', Whakatane, 12-14 November 1987, YCBN 5990 18a Part I of III, ANZA.

<sup>42</sup> 'Report on Scientific Meeting on Control of Hepatitis B Infections in Infants and Children in High Risk Areas of the World Held in Whakatane 12-14 November 1987', December 1987, YCBN 5990 18a Part II

Milne and Moyes supported this approach in less developed countries; nevertheless, they had a more expansive vision for New Zealand, based both on their own research and the comprehensive Alaskan approach to hepatitis B prevention. In 1983, the Alaska Area Native Health Service began a dedicated public health programme to stop the spread of hepatitis B among the 63,000 Alaskan Natives living in the state. This programme aimed to immunise people of all ages, including newborn babies.<sup>43</sup> At the Whakatane meeting, Brian McMahon presented an update of the Alaskan initiative in which he emphasised the value of mass child and adult hepatitis B immunisation.<sup>44</sup>

McMahon's report added impetus to Milne and Moyes' campaign to extend state-funded immunisation to school-aged children. While the Health Department was preparing to introduce what Ashworth described as the 'most extensive national hepatitis B immunisation programme in the world', they had a more ambitious goal.<sup>45</sup> Implementing the Alaskan model in a country with a much larger, more mobile population would require substantial resources; however, Milne and Moyes regarded Alaska as a suitable blueprint for New Zealand. In their view the expanded programme was merely the first step towards the larger project of universal childhood hepatitis B immunisation.<sup>46</sup>

The expansion to the immunisation programme, which Milne had envisaged would be well underway by December 1987, was in fact still at the planning stage as the 'Christmas break' approached.<sup>47</sup> A ministerial decision to invite vaccine manufacturers to re-tender for the Health Department contract, which was justified in view of the

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of III, ANZA; N. Ashworth, 'Letter to the Editor: Hepatitis B immunisation', *NZMJ*, 101, 11 May 1988, p.244-5.

<sup>43</sup> B. J. McMahon, W. L. Heyward, D. Ritter, R. B. Wainwright, E. R. Rhoades, E. Tower, A.P. Lanier, C. Helminiak, 'A comprehensive programme to reduce the incidence of hepatitis B virus infection and its sequelae in Alaskan Natives', *Lancet*, 330, 8568, 14 November 1987, pp. 1134-6.

<sup>44</sup> 'Medical warrior of Alaska sees hope in NZ research', *NZH*, 14 November 1987.

<sup>45</sup> N. Ashworth, 'Hepatitis B: Why we have to immunise', *Health*, Autumn 1988, p.3.

<sup>46</sup> Milne and Moyes promoted hepatitis B immunisation for school children at public gatherings, in media statements, in correspondence with the Health Department, and at official meetings. See, for example: 'Hepatitis B expert visits Morrinsville', 28 October 1987; 'Call for broader immunisation programme', *South Waikato News*, 8 March 1988; Minutes of the Department of Health Working Party for the Implementation of Hepatitis B Immunisation in New Zealand, 23 December 1987, ABQU 632 W4452/702 131/171/4 63088, ANZW.

<sup>47</sup> In New Zealand, Christmas festivities in late December and lengthy summer holidays during January have a disruptive effect on official activities and act as a distraction from public health issues.

favourable prices obtained, led to unanticipated delays.<sup>48</sup> For the CDCAC, which was well aware of the difficulties that had arisen during the meningococcal immunisation campaign, any delay was welcome. The committee regarded careful planning and public education as vital to the success of the hepatitis B immunisation programme. In mid-December 1987, Dr Rod Ellis-Pegler, a member of the Hepatitis B Subcommittee of the CDCAC and a former Chairman of the MRC Working Party on Viral Hepatitis, wrote to the Health Department to express his ‘genuine concern’ at the haste with which the new policy was being introduced:

Given the behaviour of New Zealanders throughout late December and the whole of January it just seems ... unreal to try and introduce the most complex immunisation schedule that we’ve ever had to do for a single vaccine [by the end of February] ... on this occasion it ... would seem sensible to allow a few more months to pass by ... it seems extremely important that this next vaccination programme not get off to a crippled start!<sup>49</sup>

The CDCAC were the official advisors on immunisation policy, however, as Chapter Five discussed, Milne had arguably exerted a stronger influence on hepatitis B policy from outside the health establishment during 1986 and early 1987. In late December 1987, when the working party for the implementation of the preschool programme considered whether to allow more time for publicity and professional and public education, Milne stated his ‘wish that his strong opposition to any delay in the programme be recorded’.<sup>50</sup> Despite the concerns expressed by the CDCAC, Caygill confirmed the start date of 29 February 1988. In correspondence with Milne, he expressed his thanks for the ‘very valuable expert advice’ provided by both Milne and Moyes on the implementation of the expanded programme of immunisation. Moreover, Caygill assured Milne that any delays in the planning process were simply an ‘inevitable

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<sup>48</sup> Originally, the Health Department had planned to start the expanded immunisation programme in the North Island, and then proceed to the South Island as finances allowed.

<sup>49</sup> Ellis-Pegler to McLeod, 18 December 1987, ABQU 632 W4452/702 131/171/4 63088, ANZW.

<sup>50</sup> Minutes of the Health Department Working Party for the Implementation of Hepatitis B Immunisation in New Zealand, 2 December 1987, ABQU 632 W4452/702 131/171/4 63088, ANZW.

outcome of the need for ... policy matters on a national level to be decided by staff who are both limited in numbers and have a wide variety of issues to consider'.<sup>51</sup>

It is clear therefore that Milne, in particular, put pressure on the Health Minister to accelerate the start of the preschool hepatitis B immunisation. Rather than focus on a more considered approach to the preschool campaign, Milne argued for its speedy introduction, while continuing to lobby for a further expansion of the hepatitis B policy.

### **Biculturalism and the implementation of the preschool programme**

When the Fourth Labour Government came to power in 1984, the Health Department took positive steps towards incorporating a Maori perspective in health policy.<sup>52</sup> The Department fostered a bicultural approach to health during the mid-1980s, but in 1987, its relationship with Maori faltered. Planning for the preschool campaign took place during this period, when attention to Maori health had diminished within the Health Department.

Dr Nigel Ashworth, a UK-trained occupational health specialist who arrived in New Zealand in 1986, was appointed as the National Coordinator of the Hepatitis B Immunisation Programme in early 1987, just before the first major expansion of the programme took place. Ashworth, whose international career in the oil industry had taken him from 'hard stations' such as Sarawak and the Middle East to the 'top job' in London was not necessarily well-prepared for coordinating a nationwide immunisation programme in New Zealand. He later acknowledged that 'I didn't make nearly enough attempt to get the Maori people on our side because I was a newcomer and I adopted the attitude ... that disease is disease'.<sup>53</sup> While he was aware that there was a need to encourage vaccine uptake among Maori children, Ashworth did not prioritise Maori involvement in the planning and promotion of the preschool programme.

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<sup>51</sup> Minister of Health to Milne, 9 February 1988, ABQU 632 W4452/702 131/171/4 63088, ANZW.

<sup>52</sup> For further discussion of the impact of the election of the Fourth Labour Government on Maori health, see for example, M. Durie, *Whaiora: Maori Health Development*, pp.82-98; R. Gauld, *Revolving Doors: New Zealand's Health Reforms - The Continuing Saga*, pp.72-4.

<sup>53</sup> N. Ashworth, interviewed by D. M. Jowitt, 8 February 2007.

In March 1987, the Health Department offered hepatitis B vaccine to all babies born in six 'high risk' health districts.<sup>54</sup> In these areas, maternity staff administered the first dose of vaccine to newborn babies, while family doctors gave the subsequent doses alongside other routine infant immunisations. As the previous chapter discussed, this policy focused on areas of high hepatitis B prevalence rather than high risk groups. Not only were health officials sensitive to the potential for stigmatisation and accusations of preferential treatment for Maori, but they believed that from an epidemiological perspective, all babies in high prevalence areas, regardless of ethnicity, required protection from the hepatitis B virus.

The initial expansion of the immunisation programme appeared to be relatively trouble-free, instilling confidence that the introduction of universal infant hepatitis B immunisation would be reasonably straightforward. Consequently, the Health Department gave priority to preparations for the preschool campaign, the first nationwide mass immunisation programme since the polio campaigns of the 1960s. Despite the Department's commitment to improving Maori health, however, Ashworth did not seek significant Maori input into the design of the preschool programme. His relative inexperience in the New Zealand health services and his reductionist view of disease undoubtedly contributed to this omission, but it also reflected changes in Maori representation in the Health Department in 1987.

The Health Department had espoused a bicultural approach to health from the mid-1980s, when it identified Maori health ('Oranga Maori') as a national priority from 1984 to 1985.<sup>55</sup> In his 1995 history of the Department, Derek Dow explained how Dr Ron Barker, Director-General of Health from 1983 to 1985, instigated the national Hui Whakaoranga, which was attended by Maori health professionals who advocated strongly

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<sup>54</sup> These were Northland, Auckland, South Auckland, Rotorua, Gisborne and Napier. Takapuna, on Auckland's North Shore, was included in the policy in early 1987, to overcome the fact that '3000 mothers resident in the Takapuna Health District deliver their babies in hospitals in the Auckland Health District'. CDCAC minutes, 6 March 1987, Ministry of Health Archives, Wellington.

<sup>55</sup> AJHR, 1984, E.10, p.23.

for Maori-led health initiatives.<sup>56</sup> Subsequently, Barker appointed a small Maori health project team within the Department to liaise with Maori communities, provide bicultural training for staff, and advise senior managers. His successor, George Salmond, whom Dow described as having a ‘determination to break the monocultural mould’ of the Department, took further action to incorporate a bicultural perspective in health policies and practices.<sup>57</sup>

Salmond responded readily to the ‘decisive stance’ taken by the Labour Cabinet in early 1986 on the Treaty of Waitangi, which required all government departments to consult with Maori on significant issues.<sup>58</sup> In a circular memorandum to hospital boards and area health boards, Salmond recommended that the Treaty should be integrated into the health services:

Concepts of health are firmly based in Maori culture (which according to the Treaty, has a right to official recognition and protection) and Maori people have a right to appropriate services – funded through our health system. The Department accepts this view which is in accord with the WHO principles set out in the Alma Ata Declaration of 1978 on Primary Health Care’.<sup>59</sup>

Despite Salmond’s desire to promote a stronger Maori perspective within the Department and in the delivery of health services, however, in 1987 amidst departmental restructuring and tightening fiscal constraints the Maori health project team resigned. According to Professor Mason Durie, a Maori psychiatrist and leading advocate of a bicultural approach to public health, the reasons for the team’s resignation ‘were not obvious’, nevertheless, its demise raised questions about the Health Department’s commitment to

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<sup>56</sup> D. A. Dow, *Safeguarding the Public Health: A History of the New Zealand Department of Health*, p.233.

<sup>57</sup> *ibid.*, pp.233-5.

<sup>58</sup> The Treaty of Waitangi, signed in 1840 by a representative of the British Crown and the chiefs of Maori tribes from many areas of New Zealand, is regarded as one of the foundations of New Zealand society. Mason Durie was a member of the 1988 Royal Commission on Social Policy which recommended ‘three principles relevant to social policy and the Treaty of Waitangi: partnership, participation, and protection’. M. Durie, *Whaiora: Maori Health Development*, pp.86-7.

<sup>59</sup> Department of Health, Circular Memorandum No.1986/70, cited in M. Durie, *Whaiora: Maori Health Development*, p.85.



Maori health.<sup>60</sup> It also reduced the Maori voice within the Department and the resources available to develop bicultural approaches to public health projects.

The Hepatitis B Immunisation Working Party, an advisory group to the Health Protection Programme, acted as the main planning body and forum for the issues that arose throughout the early stages of the preschool campaign.<sup>61</sup> The group met weekly from early December 1987 to late May 1988. It included representatives from a range of mainstream professional groups: Dr M.A.H. (Tony) Baird, Chairman of the New Zealand Medical Association (NZMA), Freida Moffat, principal public health nurse, Takapuna Health District, Dr Melvin (Mel) Brieseman, Medical Officer of Health, Christchurch, Dr Dell Hood, community health registrar, Auckland, Alexander Milne and Dr Chris Moyes from Whakatane Hospital, and Dr David Tipene-Leach, lecturer in Maori and Pacific health at Auckland Medical School.<sup>62</sup>

At the time, Ashworth explained that he had called on Tipene-Leach to join the group ‘to help out with the Maori and Polynesian language and cultural barriers that might occur’ during preparations for the preschool programme.<sup>63</sup> His presence was the only apparent attempt to involve Maori in the planning process. In light of the high prevalence of hepatitis B virus infection among Maori children in North Island communities, therefore,

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<sup>60</sup> *ibid.*, pp.105-6. In her critical analysis of the introduction of ‘free market’ economics in New Zealand, Jane Kelsey, a professor of law at Auckland University, described 1984-87 as the ‘heyday of the Treaty revival’. She explained that by late 1987, there was growing unease among the Labour caucus and the Cabinet over its Treaty policies. J. Kelsey, *Rolling Back the State: Privatisation of Power in New Zealand*, Wellington, 1993, pp.235-239. Eru Pomare, too, observed a change in the Health Department’s relationship with Maori in the late 1980s: ‘In the mid-1980s ... the Labour Government adopted a policy of biculturalism [and] Maori slowly evolved a strong partnership with the Department of Health. In the late 1980s this partnership was a thing of the past’. P. Laing, E. W. Pomare, ‘Maori health and the health reforms’, *Health Policy*, 29, 1994, p.146.

<sup>61</sup> Health Department, Health Research Services, ‘Hepatitis B Preschoolers Immunisation Campaign (1988/89) Process Evaluation’, 19 July 1990, Wellington, p.5, ABQU 632 W4452/705 131/171/4 67518, ANZW.

<sup>62</sup> Minutes of the Health Department Working Party for the Implementation of Hepatitis B Immunisation in New Zealand, 2 December 1987, ABQU 632 W4452/706 131/171/4 75586.

<sup>63</sup> *ibid.*

Tipene-Leach had a significant role in gaining Maori participation in the immunisation programme.<sup>64</sup>

By late 1987, Tipene-Leach was already well-acquainted with the hepatitis B issue. He had trained as a community health registrar in Auckland during 1987 after working as a general practitioner in Whakatane from 1984 to 1986, where he had been a keen advocate of Milne's community-funded immunisation campaign. Furthermore, during Dr Eru Pomare's visits to the region in August 1985, Tipene-Leach and his family had provided accommodation and much-appreciated support.<sup>65</sup> While Tipene-Leach had experience in delivering public health programmes, Ashworth appeared to have unrealistic expectations of his capacity to consult widely with Maori communities. Moreover, when the proposed Pacific representative for the working party did not eventuate, Tipene-Leach became the sole Polynesian spokesperson by default.<sup>66</sup>

Reflecting on his involvement in the Hepatitis B Immunisation Working Party and other public health committees in the late 1980s, Tipene-Leach later suggested that his contribution to the preparations for the preschool campaign was likely to have been 'much smaller ... than might be expected from the [records]'.<sup>67</sup> He explained that

... in those days ... there were very few Maori doctors [involved in public health]. It was about sitting in lots of different places, it was almost about confirming its okay because there is a Maori here. In many cases you didn't play a deep and meaningful professional role, the role that you played was more of a social [one].<sup>68</sup>

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<sup>64</sup> The 1985 Health Department hepatitis B survey of 3000 randomly selected children from around the country showed that at all ages Maori children were five times more likely to be positive for markers of hepatitis B infection, and that the carrier rate was 0.52 per cent for European children and 7.52 per cent for Maori children. M. Tobias, J. A. Miller, C. J. Clements, A. C. Patel, 'Hepatitis B in New Zealand children: the 1985 national immunization survey', pp.203-6.

<sup>65</sup> D. Tipene-Leach, interviewed by D. M. Jowitt, 25 July 2008. In his report to the Minister of Health, Pomare put Tipene-Leach and his family at the top of his list of acknowledgments. *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.92.

<sup>66</sup> Minutes of the Health Department Working Party for the Implementation of Hepatitis B Immunisation in New Zealand, 16 December 1987, ABQU 632 W4452/706 131/171/4 75586, ANZW.

<sup>67</sup> D. Tipene-Leach, interviewed by D. M. Jowitt, 25 July 2008.

<sup>68</sup> *ibid.* Mason Durie stated that 41 Maori doctors were registered in New Zealand by 1991. M. Durie, *Whaiora: Maori Health Development*.

Tipene-Leach's sense that a bicultural focus had been peripheral to the main business of the group matched Ashworth's memories of the working party. Ashworth later recalled that 'I did have a Maori doctor on the committee, David Tipene-Leach ... I remember holding a meeting, rather late on, when I added an agenda item, the Maori perspective, and [he] very politely told me, "about time"'.<sup>69</sup>

In the event, pressure to implement the immunisation campaign took priority over consultation over the most appropriate methods for reaching preschoolers in Maori and Pacific communities. Ashworth distributed educational material and advice on immunisation procedures to family doctors on 24 February, for a start date of 29 February 1988.<sup>70</sup> He apologised for the delay, explaining that it was due to 'the time-consuming need to work through the very many interacting administrative problems that accompany such an extensive programme'.<sup>71</sup> The first Auckland hui did not take place until early March 1988, despite the large Maori population in South Auckland. Participants of the hui planned to involve Maori organisations, such as the Maori Women's Welfare League, Kohanga Reo, the Maori Council, and marae committees, in the preschool programme. Immunisation clinics were already underway in many areas, however, so that belated attempts to 'prime' Maori communities had little chance of success, given the short timeframe in which they had to respond.<sup>72</sup>

In summary, Ashworth, whose area of expertise was occupational medicine and whose professional experience had largely been in the international oil industry, was unprepared for the social and cultural aspects of a mass childhood immunisation campaign in New Zealand. His relatively recent move from the UK, the tight lead-in time and broad focus of the preschool policy, as well as the reduced Maori influence within the Health

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<sup>69</sup> N. Ashworth, interviewed by D. M. Jowitt, 8 February 2007.

<sup>70</sup> Department of Health, 'Hepatitis B Information', Wellington, 24 February 1988, ABQU 632 W4452/702 131/171/4 63088, ANZW.

<sup>71</sup> Department of Health, Circular Memorandum, 1988/36, 'Extended Hepatitis B Immunisation Programme', 21 March 1988, ZABV A1073 886a, ANZA.

<sup>72</sup> Kohanga Reo, or Maori 'language nests', established in 1982, provide total immersion in Maori language and cultural practices for young children from birth to six years of age. 'Te Kohanga Reo National Trust' online, nd, available at: <http://www.kohanga.ac.nz/> (11 October 2009).

Department in 1987, all contributed to the lack of Maori involvement in the design and delivery of the preschool immunisation programme.

### **The AIDS scare**

In the early 1980s, in the US and UK, unfounded reports that the hepatitis B vaccine had been contaminated with the AIDS virus during the manufacturing process made many health professionals reluctant to accept hepatitis B immunisation. While these reports were disproved, doubts lingered over the integrity of the plasma-derived hepatitis B vaccine. During the preschool campaign, in a climate of increased parental concern over vaccine safety, rumours that the low dose vaccine was contaminated with the AIDS virus surfaced in New Zealand.

In the late 1980s, any link between AIDS and medical procedures caused public alarm. Fewer than 80 AIDS cases had been notified in New Zealand by the end of 1987, but, as a result of the exponential rise in cases in the US and Australia, the Health Department continued to predict an AIDS epidemic among New Zealanders.<sup>73</sup> During deliberations over details of the expanded immunisation policy, senior departmental officials had considered the potential for public concern over the safety of the plasma-derived hepatitis B vaccine, but decided that the ‘very heavy emphasis placed on the public relations aspects’ of the programme would be enough to dismiss parental anxieties. Moreover, the Department ascribed the adverse publicity during the 1987 meningococcal immunisation campaign to small groups of ‘known opponents to immunisation’, and felt confident that ‘press statements ... prepared for use [would] counter any damaging and inaccurate statements’ that these groups might make.<sup>74</sup>

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<sup>73</sup> AJHR, 1988, E.10, p.20. In March 1987, in his annual report to Parliament, George Salmond, the Director-General of Health, described AIDS as one of the two major issues dominating the health scene. He anticipated that by 1991 there were likely to be 500 cases in New Zealand, and by 1996, over 20,000. AJHR, 1987-90, E.10, pp.3-4.

<sup>74</sup> The best known of these ‘opponents’ was Hilary Butler, a South Auckland mother of two who became a leading spokesperson for the anti-immunisation lobby in the mid-1980s. Butler wrote to the *New Zealand Medical Journal* in July 1988 to support the views of a Tauranga GP, Dr Jonathan Kuttner, who had raised the spectre of AIDS-contaminated vaccine, claiming that ‘90% of health professionals in America have rejected plasma-based vaccine when it was offered to them for free’. J. Kuttner, ‘Letter to the Editor: Hepatitis B immunisation’, NZMJ, 11 May 1988, p.244; H. Butler, ‘Letter to the Editor: Hepatitis B

The first hint of trouble, in August 1987, demonstrated the persistence of the rumoured association between AIDS and plasma-based vaccine, even among health professionals. Dr R. J. Flight, Medical Officer of Health for Takapuna Health District, wrote to Dr Diana Lennon, a member of the CDCAC and paediatric infectious diseases specialist at Princess Mary Hospital in Auckland, to inform her that a nurse working in the hospital had told a new mother that the hepatitis B vaccine could not be guaranteed to be free of AIDS. Aware that the nurse's claims might threaten the credibility of the immunisation programme, Flight asked for a letter to be circulated to all Princess Mary Hospital staff emphasising that it was impossible to contract AIDS through the hepatitis B vaccine.<sup>75</sup>

Several weeks prior to the start of the expanded programme, in early February 1988, John Kennedy, Dunedin-based editor of the weekly Catholic newspaper, *The Tablet*, raised similar concerns about the safety of the vaccine. Kennedy, well known for his outspoken views on all aspects of New Zealand life, made an urgent request for information on the vaccine from Nigel Ashworth, with regard to the 'serious issues' he had uncovered while investigating the background to the preschool campaign. Predictably, Kennedy's first question to Ashworth was, 'why was a plasma-based vaccine chosen instead of a genetically-engineered yeast-based vaccine?'<sup>76</sup>

No further issues arose until mid-April 1988, just as the preschool campaign was gaining momentum. As Ashworth explained, the AIDS scare 'really took off' when a disaffected ex-MSD [Merck, Sharpe and Dohme] employee telephoned a late night Wellington talkback show to allege that the company's plasma-based product was contaminated with the AIDS virus. According to Ashworth, 'The wretched [man]'s confused and damaging contribution successfully terrified the wits out of several mothers [and] a drop in attendance occurred in some clinics by 10-15%.'<sup>77</sup>

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immunisation', NZMJ, 13 July 1988, p.464. Department of Health, 'Briefing Update on Hepatitis B Immunisation Programme,' February 1988, ABQU 632 W4452/706 131/171/4 75586, ANZW.

<sup>75</sup> Flight to Lennon, 'Hepatitis B Vaccination', 31 August 1987, ABQU 632 W4452/701 131/171/4 62751, ANZW.

<sup>76</sup> Kennedy to Ashworth, 9 February 1988, ABQU 632 W4452/702 131/171/4 63088, ANZW.

<sup>77</sup> Ashworth to Hadler, 11 May 1988; Ashworth to Lucas, 13 May 1988, ABQU 632 W4452/705 131/171/4 67517, ANZW.

Over the following week, National Radio and television reported claims that the vaccine was a source of AIDS in their daily news bulletins. As a result of the extensive media coverage and public sensitivity to the AIDS issue, Health Department offices around the country received a barrage of telephone calls from anxious parents.<sup>78</sup> While some parents contacted public health staff directly, others looked for reassurance from the health minister himself. Mrs C. Stiffe, representing ‘concerned parents from Kawakawa’, wrote to Caygill challenging the Government’s strong fiscal focus:

We have been told that a live virus is ... taken from American homosexual males, which would be in the high risk AIDS category [for manufacturing plasma-derived vaccine]. I understand the reason for using this source is that it is cheaper, presumably because of the current need for economy in medical spending. Our concern therefore is – by saving our children from Hepatitis ‘B’ [sic] are we putting them at risk of AIDS? ... We have been told there is a yeast-based immunisation that is available either now or soon but which is much more expensive.<sup>79</sup>

Stiffe claimed that Kawakawa parents had received little or no information on the vaccine, except what they regarded as ‘warnings’ to get their children immunised. Although they had heard a departmental representative on National Radio state that the AIDS rumour was nothing but ‘scaremongering by uninformed people’, they noted that no actual denial of the supposed facts had been made, nor was reliable information offered by the health officials on which to make an informed and intelligent decision.<sup>80</sup>

Another parent, a veterinarian, asked Caygill for data on the manufacturing method and safety of the vaccine, stating that she had contacted the Health Department for this information, only to gain the impression that her questions were ‘impertinent’. Like the Kawakawa parents, she felt ‘disenchanted with the handling of the “AIDS hoax”’ and she expressed her dislike of the paternalistic approach of the Health Department:

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<sup>78</sup> ‘Hepatitis jabs scare: Aids link to vaccine ‘not true’’, *Waikato Times*, 18 April 1988; ‘Spreading AIDS link rumours ‘terrorism’’, *AS*, 20 April 1988; ‘Vaccine rumours almost criminal’, *Bay of Plenty Times*, 21 April 1988.

<sup>79</sup> Stiffe to Minister of Health, 19 April 1988, ABQU 632 W4452/665 131/171/4 63302, ANZW.

<sup>80</sup> *ibid.*

As a consumer I would very much appreciate being given information in lay terms which shows the steps taken to prove the safety of the Hepatitis B vaccine during its production. ‘The safest vaccine’, ‘malicious rumours’, ‘terrorist tactics’, say nothing at all. If Department of Health doctors find the public's questioning their decisions an anathema, it would be valuable to employ a public relations person who could answer important questions like this.<sup>81</sup>

In the face of such stringent criticism and the potentially disastrous effects on the immunisation programme, the Minister and the Health Department acted swiftly to shore up public confidence in the preschool campaign. Caygill responded to an urgent question on the safety of the vaccine in Parliament on 21 April 1988 by assuring the House that not only had the vaccine been cleared by the WHO, but it underwent ‘65 week three stage sterilisation process which makes it certain every known virus [was] destroyed’.<sup>82</sup> In a public display of political accord, Peter Dunne, Parliamentary Undersecretary to the Minister of Health, and Opposition Associate Health Spokesperson Katherine O’Regan both offered to be vaccinated with the suspect vaccine.<sup>83</sup>

Health officials were at pains to reassure the public that the vaccine held no hidden risks for New Zealand children. George Salmond, the Director-General of Health, branded allegations that the hepatitis B vaccine could transmit AIDS as ‘almost criminal’, while Ashworth invited two international experts on hepatitis B to New Zealand at short notice to reassure the general public that the vaccine was free from AIDS.<sup>84</sup> Both Dr Stephen Hadler, epidemiologist at the CDC’s Hepatitis Division, and Milne’s long-time supporter Dr Ron Lucas arrived in Wellington to speak with local media on 26 April 1988.<sup>85</sup>

From Ashworth’s perspective, this strategy was an undoubted success. In May 1988, he wrote to Hadler that, ‘our combined efforts have turned the tide of doubt and uncertainty

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<sup>81</sup> George to Minister of Health, 22 April 1988, ABQU 632 W4452/665 131/171/4 63302, ANZW.

<sup>82</sup> Urgent Question from O’Regan, MP for Waipa, to Minister of Health, 21 April 1988, ABQU 632 W4452/665 131/171/4 63302, ANZW.

<sup>83</sup> ‘MPs in accord’, *Bay of Plenty Times*, 22 April 1988.

<sup>84</sup> ‘Vaccine rumours ‘almost criminal’’, *Bay of Plenty Times*, 21 April 1988.

<sup>85</sup> Department of Health, News Release, ‘Visit of Overseas Hepatitis B Experts’, 22 April 1988, ABQU 665 W4452/696 131/171/1 58287, ANZW.

in the minds of New Zealand parents ... Since 26 April the numbers [attending clinics] have increased again'.<sup>86</sup> In response to the broader concerns of parents who felt the Department had failed to provide adequate information on the safety of the vaccine, he followed up with a memo to Area Health Boards and Health Development Units outlining the steps taken to eliminate viral contamination during the production of the plasma-based vaccine.<sup>87</sup> Ashworth suggested that his 'detailed, but understandable' account of the manufacturing process would allay the fears of most parents. While he asserted that 'voluminous scientific data' would make little difference to 'diehard unbelievers', he advised health workers that 'it is always worth spending a little time in the attempt to reassure them'.<sup>88</sup>

The switch from plasma-derived vaccine to recombinant vaccine for the national immunisation programme in October 1989 put an end to parental concerns about AIDS contamination.<sup>89</sup> The Health Department made its decision to change vaccines for reasons of economy and supply, however, rather than to reduce parental fears. The price of recombinant vaccines had fallen as competing companies entered the market, and plasma-derived vaccines were no longer available from US vaccine manufacturers who had moved to the faster, less contentious recombinant production method.

The decision to use low dose plasma-derived vaccine, rather than the recombinant product, had a negative effect on the immunisation campaign. The Health Department came under attack for its penny-pinching approach to vaccine selection, its paternalistic response to parental concerns, and its apparent reluctance to provide appropriate information on vaccine safety. To restore public confidence in its immunisation programme, the Department turned to the authority of international experts, and it worked.

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<sup>86</sup> Ashworth to Hadler, CDC, 11 May 1988, ABQU 632 W4452/705 131/171/4 67517, ANZW.

<sup>87</sup> Ashworth to Health Development Units and AHBs, 'Safety of Plasma-derived Hepatitis B Vaccine', 17 May 1988, ABQU 632 W4452/707 131/171/4 75588, ANZW.

<sup>88</sup> *ibid.*

<sup>89</sup> Department of Health, Circular Memorandum, No 1989/146, 26 October 1989, 'Hepatitis B Change of Vaccine', ABQU 632 W4452/704 131/171/4 66798, ANZW.



## **Immunisation and Maori**

In the mid-1980s, research available to the Health Department indicated that overall levels of immunisation among New Zealand children were less than satisfactory, and that vaccine uptake was lower among children from Maori and Pacific families and those living in deprived socio-economic circumstances.<sup>90</sup> Despite these findings, the Department was confident that the hepatitis B preschool campaign would reach high risk children, and that it would achieve substantially higher coverage than most other vaccines on the childhood immunisation schedule.

From the end of February 1988, public health workers in Health Development Units and Area Health Boards around the country concentrated on broad uptake of the hepatitis B vaccine among preschoolers. Public health workers administered vaccine wherever parents and children could congregate: clinics, churches, schools, sports venues, community halls, and information centres.<sup>91</sup> Each health district concentrated on achieving high rates of immunisation regardless of risk factors, or of the prevalence of hepatitis B in their geographical area.

In early April 1988, John Stephenson reported to the Health Minister that public health nurses in Wellington, Rotorua, Timaru and Dunedin had approached the start of the preschool programme with 'enthusiasm and energy'. Nevertheless, Stephenson also acknowledged the challenges inherent in the low dose programme, which required four injections of hepatitis B vaccine to be given over a year. He wrote that 'the practical logistics of organising clinics to give pre-schoolers four injections of vaccine [over] 12 months requires sustained publicity and recruitment of temporary clerical staff to supervise clinic arrangements and proper recording of doses'.<sup>92</sup>

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<sup>90</sup> For further discussion of immunisation levels in the 1980s see A.S. Day, 'Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920 –1990', pp.288-92, also F. T. Shannon, D. M. Fergusson, M. A. Clark, 'Immunisation in the first year of life', NZMJ, 12 March 1980, pp.169- 71; M. A. Soljak, 'How many children are fully immunised?', NZMJ, 97, 25 January 1984, pp.37-9.

<sup>91</sup> Northland Area Health Board, 'Free Hepatitis B immunisation for Preschool Children', 15 June 1988, ABQU 632 W4452/1865 361/3/3/5 74664, ANZW.

<sup>92</sup> Stephenson to Minister of Health, 'Hepatitis B Immunisation Programme: Progress', 5 April 1988, ABQU 665 W4452/707 131/171/4 63302, ANZW.

The short time frame for planning had delayed the start of the preschool programme in some health districts, but by mid-1988, most areas had almost completed the third round of immunisation. It was at this point that senior health officials began to question the rates of vaccine uptake. In early June 1988, George Salmond, the Director-General of Health, gave the first indication that participation in the programme might not be as high as had originally been anticipated. Preliminary data showed that only 73 per cent of preschoolers around the country had received their first hepatitis B vaccine injection, which was somewhat lower than the departmental target of 80 per cent.<sup>93</sup>

Whether this target was ever realistic is open to debate; two Health Department surveys undertaken in 1985 revealed that up to 30 per cent of New Zealand children did not receive their routine immunisations against vaccine-preventable diseases.<sup>94</sup> Nonetheless, health officials expected single issue campaigns, which had a higher profile and more intensive publicity than routine immunisations, to achieve higher immunisation rates. During the 1987 meningococcal campaign in Auckland, for example, before the public furore over vaccine safety, more than 90 per cent of eligible preschool and school children received their initial immunisation.<sup>95</sup> As a preventive measure, the meningococcal campaign had been highly successful, and even though only one or two doses of vaccine had been given in a relatively small geographical area, the Health Department had reason for guarded optimism in the national hepatitis B campaign.<sup>96</sup>

In mid-1988, in a belated change of strategy, the Department directed regional public health workers to give more consideration to targeting 'high-risk groups'.<sup>97</sup> In a memo to

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<sup>93</sup> Department of Health, Circular Memorandum, 'Hepatitis B Immunisation Programme', 9 June 1988, ABQU 632 W4452/707 131/171/4 75588, ANZW.

<sup>94</sup> In surveys undertaken in the mid-1980s, less than 75 per cent of school entrants were fully immunised against diphtheria, pertussis, tetanus and measles. R. Lau, K. A. Bettelheim, A. C. Patel, 'The 1985 national immunisation survey: diphtheria, tetanus, and pertussis (whooping cough)', NZMJ, 101, 23 November 1988, pp.797-800; M. Tobias, J. Scadden, J. Clements, A. C. Patel, 'Measles immunity in children: the 1985 national immunisation survey', pp.315-7.

<sup>95</sup> 'Meningococcal Meningitis Immunisation Campaign in Auckland 1987', ABQU 632 W4415/918 67372 144/39, ANZW, cited in A. S. Day, 'Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920-1990', p.259.

<sup>96</sup> *ibid.*, p.257; Holdaway to DGH, 1 December 1987, ABQU 632 W4452/ 707 131/171/4 75588, ANZW.

<sup>97</sup> Ashworth to Health Development Units and AHBs, 10 June 1988, ABQU 632 W4452/702 131/171/4 63088, ANZW.

area health boards and public health staff, Ashworth noted that as fewer children were presenting at clinics for their second and third immunisations, there should be a shift in emphasis: ‘any cost and effort should be concentrated in high prevalence areas ... and in high prevalence groups – i.e. those social groups known to have high proportions of the disease’.<sup>98</sup> In August 1988, Stephenson provided an update on the hepatitis B immunisation programme to the Health Department’s Finance Division. Of the estimated 220,000 preschoolers, he reported that ‘74% (162,800) had received their first injection, 78% of these received the second (126,984) and 75% of these have completed the three injections (122,100)’.<sup>99</sup> While these results were disappointing, ten months later, in June 1989, further analysis revealed marked ethnic differences in immunisation rates: 63 per cent of non-Maori and 34 per cent of Maori preschoolers had received their third dose of vaccine.<sup>100</sup>

These figures pointed to deficiencies in the planning and implementation of the preschool programme. While cost containment had been an overriding factor in the decision to target preschoolers, the Department had looked to Alexander Milne’s success in recruiting preschool children during his community-funded programmes, and to the uptake achieved among preschoolers during the Auckland meningococcal A campaign in mid-1987.<sup>101</sup> However, Milne had used innovative methods to raise public awareness of hepatitis B, and the severity of meningococcal disease contributed to the high immunisation rates during the Auckland campaign. As Alison Day explained, a public health nurse who achieved 99 per cent uptake at two schools with predominantly Maori and Pacific rolls attributed her success to ‘the high levels of motivation within the [local] community because “children were dying and people knew people who had lost them”’.<sup>102</sup>

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<sup>98</sup> *ibid.*

<sup>99</sup> Department of Health, Minutes of the meeting of the Division of Finance, 24 August 1988, ABQU 632 W4452/702 131/171/4 64449, ANZW.

<sup>100</sup> Health Services Research Delivery Unit, ‘National Estimate of Compliance: Hepatitis B Immunisation Programme’, draft report, June 1989, ABQU 632 W4452/704 131/171/4 66405, ANZW.

<sup>101</sup> A. S. Day, ‘Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920–1990’, p.257.

<sup>102</sup> *ibid.*, p.280.

An extensive media campaign had been undertaken before the start of the expanded hepatitis B immunisation programme, but it had been aimed primarily at the general population, rather than at 'high risk' communities. A study undertaken in South Auckland in May and June 1988 suggested that personal contact was a more effective means of reaching parents 'who traditionally lack access to health services and whose children are also in a high-risk group for hepatitis B infection'.<sup>103</sup> The parents interviewed, many of whom were Maori or Pacific people living in lower socio-economic suburbs, cited difficulty getting to the immunisation clinics, lack of understanding of the importance of the vaccine, and fear of side-effects and AIDS as reasons for non-participation in the programme. Furthermore, only 65 per cent of the South Auckland parents compared with 97 per cent of Hutt Valley households surveyed for the Health Department had heard of the hepatitis B immunisation programme.<sup>104</sup>

Leading Maori health professionals regarded the low vaccine coverage as an indication of the failure of mainstream health providers to meet the specific needs of Maori. Speaking at the Hui Hauora Mokopuna in mid-1990, Professor Eru Pomare concluded that the results of the preschool immunisation programme among Maori had been 'disappointing'. Pomare suggested that 'Perhaps Maori ... could develop a service which is more successful [and which] better suits Maori needs'. Moreover, David Tipene-Leach, the sole Maori representative on the Working Party for the National Hepatitis B Programme, described the poor immunisation rates among Maori preschoolers as 'less than equitable'.<sup>105</sup>

Judith Webb-Pullman, who completed a public health dissertation on the preschool immunisation programme in late 1990, argued that low Maori representation among the policy making elite was a critical factor in the perpetuation of the 'enormous disparities

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<sup>103</sup> L. Calder, *What is the Best Way to Inform High-Risk Groups about Hepatitis B Immunisation? A Survey by Polynesian Community Health Workers, South Auckland Health Development Unit* unpublished paper, 1988, personal possession.

<sup>104</sup> *ibid*; C. Hadley, 'Cost effectiveness of the pre-school hepatitis B immunisation programme at Hutt Health Development Unit 1988: a preliminary assessment', Wellington, August 1988, ABQU 632 W4452/707 131/171/4 75588, ANZW.

<sup>105</sup> Ministerial Advisory Committee on Maori Health, *Hui Hauora Mokopuna: Ratana Pa, 22-24 June 1990*, Wellington, 1990.

in health status between Maori and non-Maori'.<sup>106</sup> Further, she considered moves by the Health Department to 'co-opt' Maori and develop more 'culturally appropriate and acceptable' health services, did not 'address the fundamental problem: they are Pakeha institutions, using Pakeha methods to define Pakeha problems in Pakeha terms, and seeking Pakeha-defined solutions'.<sup>107</sup> From the Maori perspective, Webb-Pullman described the preschool programme as 'an abysmal failure in respect of efficiency and responsiveness'.<sup>108</sup>

While the intent of the Hepatitis B Immunisation Working Party had apparently been to 'achieve the highest possible coverage [among preschoolers] in areas of high prevalence', the majority of its planning, and its public relations effort, had a broader focus.<sup>109</sup> The results of this oversight were evident in an evaluation report completed for the Health Department in mid-1990, in which public health units reported that they had not had the staff, funding, or time to develop effective, culturally appropriate methods to reach Maori or Pacific groups.<sup>110</sup> General issues, such as the lengthy four dose immunisation schedule, and the reliance on parents to bring preschool children to immunisation clinics, had an effect on the overall uptake of the vaccine, but they had a more profound impact on the immunisation rates among Maori.<sup>111</sup>

### **Public and professional pressure to expand hepatitis B immunisation**

By implementing a policy of infant and preschool immunisation, the Health Department had believed that it would protect 'a particularly vulnerable group, more liable to suffer

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<sup>106</sup> J. Webb-Pullman, 'The Hepatitis B Preschool Immunisation Programme: A Case Study in Institutional Racism', Dissertation for the Diploma of Public Health, Wellington Clinical School of Medicine, 1990, pp.39-40.

<sup>107</sup> *ibid.*

<sup>108</sup> *ibid.*, pp.44-5.

<sup>109</sup> Minutes of the Health Department Working Party for the Implementation of Hepatitis B Immunisation in New Zealand, 3 February 1988, ABQU 632 W4452/706 131/171/4 75586, ANZW.

<sup>110</sup> Health Research Services, 'Hepatitis B Preschoolers Immunisation Campaign (1988/89) Process Evaluation', 19 July 1990, Wellington, pp.37-43, ABQU 632 W4452/705 131/171/4 67518.

<sup>111</sup> C. Hadley, Wellington Region Health Development Unit, 'Cost-effectiveness of the Pre-School Hepatitis B Immunisation Programme at the Hutt Health Development Unit 1988: A Preliminary Assessment', ABQU 632 W4452/707 131/171/4 75588.

mild infection with hepatitis B which results in the chronic carrier state'.<sup>112</sup> With the less than satisfactory vaccine uptake during the preschool campaign, however, Health Minister David Caygill found himself under increasing pressure from the public and from health officials to expand the hepatitis B immunisation programme to school-aged children.<sup>113</sup>

In late 1987 and early 1988, in its public relations campaign promoting hepatitis B immunisation for infants and preschoolers, the Health Department had stressed the importance of preventing infection and the subsequent development of the chronic carrier state. While the public appeared to accept that babies and preschoolers should be immunised for hepatitis B, the rationale for limiting the extent of the programme was not so widely understood. In correspondence with Caygill in May 1988, for example, parents and teachers from Ngongotaha, Rotorua, expressed the view that the decision to immunise younger rather than older children was arbitrary: 'it is our opinion that primary school children are equally at risk and we cannot see why a distinction should be made between the two groups'.<sup>114</sup>

Other schools, such as Petone Central, saw the immunisation of school children as a 'natural' sequel to the preschool programme. The school planned to follow Milne and Moyes' lead in the Eastern Bay of Plenty by providing their own immunisation scheme. In a letter to the Minister of Health, the school secretary asked for financial support: 'We would like to know whether there is any intention to extend the ... pre-school inoculation campaign to primary school children. If not, [can we] apply for a subsidy to assist us in meeting our inoculation costs'.<sup>115</sup>

Some health professionals, too, regarded the expansion of hepatitis B immunisation to older children as essential, given the poor vaccine uptake among preschoolers. In

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<sup>112</sup> Office of the Minister of Health, Memorandum for Cabinet, 'National Hepatitis B Immunisation Programme', 18 June 1987, ABQU 632 W4452/702 62752.

<sup>113</sup> Department of Health, Circular Letter to Medical Practitioners 1/88, 19 February 1988, ABQU 632 W4452/702 131/17/4 64448, ANZW.

<sup>114</sup> Spurdle to Minister of Health, 22 May 1988, ABQU 632 /702 131/171/4 64448, ANZW.

<sup>115</sup> Shramka to Minister of Health, 21 June 1988, ABQU 632 W4452/702 131/171/4 64448, ANZW.

Northland, a high hepatitis B prevalence area, immunisation rates among preschoolers had been particularly disappointing. The Northland Area Health Board set up special clinics were for 'late starters' in July 1988, but public health officials did not anticipate major increases in vaccine uptake. Dr David Sloan, Medical Officer of Health for Northland, told the *Northern Advocate* that 'we have to be realistic. Public health nurses have already devoted time and effort to the local clinics ... there is only so much time we can dedicate to hepatitis B'.<sup>116</sup>

In correspondence with John Stephenson, Manager of the Health Protection Programme, Sloan argued that the low vaccine uptake among preschoolers was a legitimate reason for extending the programme to school children:

Our senior management group is considering whether we should recommend an extension of the Hepatitis B programme to school children, as a local initiative ... The most optimistic estimate for the uptake of all four doses of vaccine among preschoolers in Northland is 60% of those at present unprotected. This shortfall is another reason to extend the programme to catch the 5-10 year olds. The logistic advantages of a "captive" population, the high risk of infection in 5-7 year olds ... and the public questioning of the absence of such a programme, are no doubt well known to you.<sup>117</sup>

Nigel Ashworth replied to Sloan on Stephenson's behalf, explaining that the extension of the existing programme would ultimately depend on the funding available. He stated that while 'there [wa]s a strong body of medical opinion supporting the further extension of the national immunisation programme to include children up to 10 years of age ... the Department was still concentrating on the pre-school programme'. Ashworth informed Sloan that the question of subsequent extension of the programme had been referred to the CDCAC at its meeting in mid-August 1988.<sup>118</sup>

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<sup>116</sup> '1200 children still at risk from hepatitis B', *Northern Advocate*, 15 July 1988.

<sup>117</sup> Sloan to Stephenson, 'Hepatitis B Immunisation for School Age Children', 12 July 1988, ABQU 632 W4452/702 131/171/4 64448, ANZW.

<sup>118</sup> Ashworth, to Sloan, 'Hepatitis B Immunisation for School Age Children', 14 July 1988, ABQU 632 W4452/702 131/171/4 64448, ANZW.

At this meeting, the CDCAC was advised that the Health Protection Programme was applying for funding to expand the hepatitis B immunisation programme. After an update on the low immunisation rates achieved among preschoolers in high prevalence health districts, the CDCAC recommended that any expansion should include a ‘catch-up’ programme at school entry. In addition, the committee proposed that the low dose immunisation campaign should be extended to all school children from five to ten years of age, and to household and sexual contacts of hepatitis B carriers. In the interim, it recommended that the focus should remain on the newborn and preschool programmes, to ensure that all children less than five years of age received at least three of the four doses of vaccine on the low dose schedule.<sup>119</sup>

The preschool campaign, which emphasised the serious sequelae of hepatitis B virus infection in early childhood, drew public and professional attention to the importance of hepatitis B prevention. While some communities regarded school-based hepatitis B immunisation as the obvious next step after the preschool programme, others were convinced that older children were in urgent need of protection. Among public health workers, the lacklustre results of the preschool campaign gave rise to pressure to shift the focus of immunisation policy to school-aged children.

### **User pays hepatitis B immunisation**

In late 1988, with calls for further fiscal restraint and efficiency measures in health, a proposal for a ‘user pays’ hepatitis B immunisation scheme for school children found favour with senior health officials. However, the decision to allow one user pays programme to operate led to the unanticipated appearance of competing schemes which intensified the pressure on the Government to expand the state-funded childhood hepatitis B immunisation programme.

During the first term of the Fourth Labour Government (1984–1987), the Finance Minister Roger Douglas introduced radical reforms to de-regulate the economy and lower the financial deficit. In early 1987, in an attempt to reduce Government spending,

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<sup>119</sup> CDCAC minutes, 18 August 1988, Ministry of Health Archives, Wellington.



Douglas suggested that the concept of user pays, originally devised as a measure to reduce the cost of government services in farming and industry, could also be applied to social services and health care.<sup>120</sup> While the Prime Minister, David Lange, rejected this proposal, Douglas' economic philosophy found favour among some members of the Labour Cabinet, including Michael Bassett, and the Health Minister, David Caygill.<sup>121</sup>

In August 1988, senior health officials asked Caygill to consider a further expansion of the hepatitis B immunisation programme. Caygill delayed his decision; four months later, he had still given no indication as to whether he approved of the concept or whether funding would be available. Larger issues were looming within the Labour Government. In mid-December 1988, the long-standing conflict between Lange and Douglas erupted, Douglas resigned, and a week later, Lange narrowly survived a leadership challenge. Caygill accepted the Finance portfolio in late December 1988, retaining nominal control of his previous position until Helen Clark was appointed Minister of Health in a Cabinet reshuffle at the end of January 1989.<sup>122</sup>

During this period of political upheaval, the US-based vaccine company Smith Kline and French (SKF) approached the Health Department with a proposal to provide subsidised vaccine and vaccinators on a user pays basis for school-aged children. Under the SKF scheme, only the children whose parents could afford the \$40 fee would be immunised. From the company's perspective, the high level of public interest and the limits to the

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<sup>120</sup> Douglas introduced the concept that the individual rather than the government should pay for some essential services as an integral part of so-called 'Rogernomics' economic management. C. James, *New Territory: The Transformation of New Zealand 1984-92*, Wellington, 1992, pp.224-33; pp.256-8; J. Kelsey, *The New Zealand Experiment: A World Model for Structural Adjustment?*, Auckland, 1995, pp.31-5.

<sup>121</sup> In 1986, Michael Bassett, the Minister of Health, commissioned business leader, Alan Gibbs to head a taskforce on hospitals and health services. Even though 'Unshackling the Hospitals', better known as the (1988) 'Gibbs Report', had no immediate effect on health policy, it introduced market concepts to health, and pointed the way for the radical reforms instigated by the National Party in the early 1990s. J. Martin and G. Salmond, 'Policy making: The messy reality', in P. Davis and T. Ashton, *Health and Public Policy in New Zealand*, p.48. Jane Kelsey, an outspoken critic of free market economic policies, described David Caygill as one of Douglas' 'two main associates' in the Labour Cabinet. *The New Zealand Experiment: A World Model for Structural Adjustment?*, p.32.

<sup>122</sup> M. Bassett, *Working with David: Inside the Lange Cabinet*, p.456; pp.466-7.

hepatitis B immunisation policy warranted a commercial proposition of this kind.<sup>123</sup> In a political climate that encouraged fiscal savings and less state intervention, the Health Department agreed to the SKF proposal. By February 1989, however, senior officials were beginning to express doubts about the ethical aspects of school-based user pays immunisation programmes. The new Health Minister Helen Clark was known to hold strong views on the role of the Health Department, and its relationship with the private sector.<sup>124</sup> SKF, which wanted to offer immunisations from the start of the school year, requested endorsement of their ‘vaccine service’ from the Department. George Salmond, the Director-General of Health, delayed his response until he had raised the SKF proposal with Clark.<sup>125</sup>

Once advised of the SKF scheme, Clark was quick to raise her concerns. In correspondence with Sally Shaw, the Manager of Population Policy, in February 1989 Salmond stated that both the Department’s association with a commercial organisation and the equity issues inherent in a user-pays programme ‘troubled’ Clark.<sup>126</sup> He outlined her main objections to the programme: ‘Children of wealthy families will be immunised – poor children, brown children, those at greatest risk will not.’ Moreover, she anticipated political fallout from the scheme: ‘the associated publicity will pressure the Government to bring forward a public programme to immunise 5-14 year olds. [Without] such publicity we may not have given such a programme the highest priority in a public health sense’. Given that the Department had already made a commitment to the SKF programme, however, Salmond reported that Clark was pragmatic about the outcome; ‘If

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<sup>123</sup> Shaw to Minister of Health, ‘Smith Kline & French Hepatitis B Vaccine Service to Schools – Progress Report’, 21 February 1989, ABQU 632 W4452/703 131/171/4 65315, ANZW.

<sup>124</sup> Clark expressed these views very strongly in a memo to Salmond in early March 1989, in which she reminded him that with regard to hepatitis B immunisation, ‘it is the Department’s responsibility to determine its priorities according to its assessment of the overall public good. It should not be influenced by pressure from a particular company or sectional interest’. Minister of Health to DGH, 9 March 1989, ABQU 632 W4452/703 131/171/4 65315, ANZW.

<sup>125</sup> Shaw to Minister of Health, ‘Smith Kline & French Hepatitis B Vaccine Service to Schools – Progress Report’, 21 February 1989, ABQU 632 W4452/703 131/171/4 65315.

<sup>126</sup> DGH to Shaw, ‘SKF – Hepatitis B’, 21 February 1989, ABQU 632 W4452/703 131/171/4 65315, ANZW.

everything goes well, she accepts that, say in about a year's time, we may be able to run a well targeted publicly run programme and pick up the residue.'<sup>127</sup>

The SKF hepatitis B campaign did attract publicity, but of the most controversial kind. In her regular *Dominion Sunday Times* column, health activist Sandra Coney observed that a double page advertisement in the *New Zealand Listener* in February 1989 promoting the immunisation of the whole New Zealand population against hepatitis B raised 'the issue of AIDS and blood-based vaccines while saying such fears were unfounded ... as the material emerged in a public atmosphere of hysteria about AIDS it was seized upon by the media'.<sup>128</sup> The lack of company branding on the advert concerned Coney even more; without an obvious source, she argued that the public was likely to attribute the text and graphics to the Health Department.<sup>129</sup>

After pressure from the Department, SKF agreed to pull their advertising campaign, but it did not change the promotional material intended for distribution to families. Both the Auckland and Otago Area Health Boards contacted the Department to query the company's tactics and to complain about the nature of their marketing strategy:

... the first piece of information is that Hepatitis B is more infectious than AIDS. This cannot be denied, however, the juxtaposition of these two diseases implies that they [are] of a similar nature, which of course they are not. Secondly, there is an implication that playing rugby or netball puts one at high risk ... this is another example of how a drug company is trying to use marketing tactics to reach a sensitive spot in many New Zealanders.<sup>130</sup>

Alexander Milne and Chris Moyes also objected to the SKF immunisation scheme, but for different reasons. They claimed that when blanket immunisations were offered

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<sup>127</sup> *ibid.*

<sup>128</sup> S. Coney, 'Have a Shot', in *Out of the Frying Pan: Inflammatory Writings 1972-89*, Auckland, 1990, p.190. See also, Ashworth to DGH, 'Smith Kline and French', 9 February 1989; Tilson to DGH, 'Hepatitis B Immunisation', 18 February 1989, ABQU 632 W4452/703 131/171/4 65315, ANZW.

<sup>129</sup> S. Coney, 'Have a Shot', in *Out of the Frying Pan: Inflammatory Writings 1972-89*, p.190.

<sup>130</sup> McLeod to DGH, 'Smith Kline & French (SK&F) Hepatitis B Immunisation Programme', 17 March 1989; Dickson to Poutasi, Department of Health, 5 April 1989, ABQU 632 W4452/703 131/171/4 65315, ANZW.

without a prior blood test, children who were already immune or were chronically infected with the hepatitis B virus would be charged up to \$45 for a vaccine that they did not need. Further, as Chapter Seven will discuss, Milne and Moyes had a broader agenda of establishing a national register of hepatitis B carriers so as to provide identified carriers with a programme of regular surveillance modelled on the scheme developed by the Alaska Area Native Health Service.<sup>131</sup>

In 1988, Milne had begun to seek support for a targeted hepatitis B immunisation programme for 'high risk' school children, which involved pre-immunisation blood tests to identify those children who were carriers, and immunisation for those children susceptible to the disease. By late February 1989, he had written to over 100 primary schools in Auckland and the Waikato region asking them to consider the 'Whakatane plan' which would offer pre-immunisation hepatitis B screening and immunisation for \$20 per child, with approximately \$11 paid by parents and the rest raised through community fund raising.<sup>132</sup> Milne was aware that many Maori were eager for the hepatitis B immunisation programme to be expanded to include school-aged children, and in March 1989 he lobbied Maori leaders to support his proposal.<sup>133</sup>

The Health Department initially took a positive approach to Milne's activities. In a detailed memo to Clark on 3 March 1989, Shaw suggested that Milne's plan offered two possible advantages: it went some way to addressing the problem of inequitable access to hepatitis B immunisation, and it had the potential to put pressure on SKF to lower the price of its vaccine.<sup>134</sup> The Department was already involved in implementing changes in the public health sector, and Shaw recommended that a publicly funded extension to the

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<sup>131</sup> The Alaskan service provided six-monthly medical follow up for adult hepatitis B carriers to detect signs of cirrhosis and liver cancer. B. J. McMahon, W. L. Heyward, D. Ritter, R. B. Wainwright, E. R. Rhoades, E. Tower, A.P. Lanier, C. Helminiak, 'A comprehensive programme to reduce the incidence of hepatitis B virus infection and its sequelae in Alaskan Natives'.

<sup>132</sup> 'Hold off jabs, asks researcher', *Sunday Star*, 26 February 1989.

<sup>133</sup> A. Milne, 'Hepatitis B control in high risk primary schoolers', Record of a meeting held in the Department of Maori Affairs, 1 March 1989, ABQU 632 W4452/703 131/171/4 75858, ANZW.

<sup>134</sup> Shaw to Minister of Health, 'Hepatitis B Immunisation Programme', 3 March 1989, ABQU 632 W4452/703 131/171/4 65315, ANZW.

hepatitis B programme should be deferred until 1990.<sup>135</sup> Moreover, departmental officials believed that ‘catch-up’ immunisations for high risk preschool children and delivering the fourth dose of vaccine were higher priorities than starting an entirely new immunisation programme for more than 500,000 school children aged from five to sixteen years.<sup>136</sup>

As Clark had predicted, the response to the SKF vaccine programme varied greatly throughout the country. The South Island, which had a lower prevalence of hepatitis B, had a higher vaccine uptake, whereas in the North Island, fewer children were being immunised in lower socio-economic areas, and high prevalence districts, such as South Auckland. According to correspondence from school principals forwarded by Milne to the Health Department, less than a dozen children were immunised out of a roll of several hundred at Mangere Intermediate School, and at Kedgley Intermediate School, Papatoetoe, only 70 out of 500 children participated in the SKF programme.<sup>137</sup> The inequities of this situation were not lost on the national Parents and Teachers Association which called on the Health Department to provide free vaccine for ‘at risk’ children: ‘Where is the [Department] in this hour of need? Further abdication of responsibility in cutting budgets?’<sup>138</sup>

In June 1989, Milne and the Whakatane-based HRU began pre-immunisation screening and immunisation in schools in high hepatitis B prevalence areas.<sup>139</sup> The HRU was not the only group to respond to public interest in hepatitis B immunisation; family doctors in a number of areas began offering vaccine through local schools which they funded by claiming the General Medical Services Benefit.<sup>140</sup> One South Auckland medical practice,

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<sup>135</sup> AJHR, 1989, E.10, pp.3-4.

<sup>136</sup> Shaw to Minister of Health, ‘Hepatitis B Immunisation Programme’, 3 March 1989, ABQU 632 W4452/703 131/171/4 65315.

<sup>137</sup> Secretary, Mangere Intermediate School, to Milne, ‘Blood Testing for Hepatitis B’, 12 June 1989; Principal, Kedgley Intermediate School, to Milne, 20 June 1989, ABQU 632 W4452/704 131/171/4 66405, ANZW.

<sup>138</sup> Anon., ‘Hepatitis B immunisation’, *Parent & School*, 20, 2, April 1989, pp.20-1.

<sup>139</sup> Milne to Minister of Health, ‘Hepatitis B in Polynesian Schoolchildren’, 3 July 1989, ABQU 632 W4452/704 131/171/4 66405, ANZW.

<sup>140</sup> The GMS Benefit was double the Immunisation Benefit of \$7.65, which was paid to doctors by the Health Department for immunising children when the vaccine was on the national childhood immunisation schedule. Minister of Health, Memorandum for Cabinet Social Equity Committee, 10 October 1989, ABQU 632 W4452/704 131/171/4 66798, ANZW.

Central Medical, also began offering free screening prior to immunisation. By Vivien Edwards' account, the Central Medical scheme emerged as a result of a donation of 10,000 doses of vaccine from SKF, which also provided the Lions Club of New Zealand, a community service organisation, with 3,300 courses of vaccine free for children from 'families in genuine need'.<sup>141</sup>

Milne was quick to alert the Health Department to the challenge from Central Medical, alleging that it intended to fund its screening programme by claiming state-funded laboratory benefits.<sup>142</sup> In a memo to Clark in late June 1989 which noted the emergence of multiple private providers offering hepatitis B vaccine for school children, Stephenson assured her that departmental staff were monitoring the situation. With reference to the Central Medical scheme, he observed that it 'highlight[ed] the level of pressure ... being placed on the department and your office to consider immunising primary school children as a priority'.<sup>143</sup>

The decision to endorse the SKF user pays hepatitis B immunisation programme was later described by Dr Karen Poutasi, Chief Health Officer in the Health Department, as 'a learning experience ... [with] many difficulties which were totally unforeseen'.<sup>144</sup> While the publicity associated with the programme increased public anxieties about the risks of hepatitis B virus infection in childhood, the unexpected appearance of competing private vaccine initiatives, some of which required caregivers to contribute towards the costs of immunisation, undoubtedly increased the pressure on Clark to expand the state-funded hepatitis B immunisation programme.

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<sup>141</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.53; Beckwith to Health Department Health Educators, 'Hepatitis B Immunisation Programme of SKF and Lions Clubs of New Zealand', 23 June 1989, ABQU 632 W4452/704 131/171/4 66406, ANZW.

<sup>142</sup> Stephenson to Minister of Health, 'Hepatitis B immunisation in Schools', 23 June 1989, ABQU 632 W4452/703 131/171/4 66639, ANZW.

<sup>143</sup> *ibid.*

<sup>144</sup> Poutasi to Dickson, 3 May 1989, ABQU 632 W4452/703 131/171/4 66406, ANZW.

### **Immunisation for school-aged children**

Helen Clark was willing to consider an expansion of the hepatitis B immunisation programme, but she was reluctant to provide pre-immunisation screening or to introduce a policy that targeted Maori children. Ethnically targeted hepatitis B immunisation, first suggested in 1986, had raised the politically sensitive issues of stigmatisation and equitable access to public health programmes.<sup>145</sup> Clark, who was committed to the universal provision of public health services, saw more merit in making hepatitis B childhood immunisation widely accessible through family doctors who administered all other vaccines on the routine childhood immunisation schedule.

In mid-July 1989, Clark met with Sally Shaw, the Manager of Population Policy, to discuss the hepatitis B immunisation programme. Shaw advised Clark that after completing the preschool programme, the Health Department was in favour of expanding state-funded immunisation to primary school children.<sup>146</sup> With regard to the pressure being exerted by Alexander Milne to provide pre-immunisation screening for ‘high risk’ children, she presented two options: the first to immunise approximately 350,000 New Zealand children from six to twelve years of age at a cost of \$2.1 million, and the second to include pre-immunisation screening for children in six high prevalence areas at a cost of \$3.23 million.<sup>147</sup>

Shaw explained that neither the Department nor the CDCAC regarded pre-immunisation screening as essential if the main objective of the policy was to protect susceptible children from the hepatitis B virus.<sup>148</sup> Not only did the CDCAC regard pre-immunisation screening as ‘very wasteful of resources’, but it considered that there was no risk, in terms of harmful side-effects, in immunising children who had previously been infected by the virus.<sup>149</sup> In addition, as Chapter Seven will discuss, the CDCAC was unwilling to

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<sup>145</sup> See Chapter Five for a full discussion of the issues raised in response to a proposal to introduce an ethnically-targeted hepatitis B immunisation programme in late 1986.

<sup>146</sup> Shaw to Minister of Health, ‘Hepatitis B Immunisation Programme, Appendix 1: Department of Health Strategy on Hepatitis B Immunisation’, 21 July 1989, ABQU 632 W4452/703 131/171/4 66639, ANZW.

<sup>147</sup> *ibid.*

<sup>148</sup> Minutes of the CDCAC, 6 April 1989, Ministry of Health Archives, Wellington.

<sup>149</sup> *ibid.*

support screening to detect hepatitis B carriers when no effective treatment for chronic hepatitis B virus infection was available.

Clark reserved her decision on vaccine policy as tensions increased within the Labour Cabinet. Changes to the leadership of the Labour Government were imminent. On 7 August 1989, David Lange resigned, and on 8 August 1989, Geoffrey Palmer was sworn in as Prime Minister with Clark as his Deputy.<sup>150</sup> During this period of political turmoil, Maori communities expressed concern that Clark was reluctant to act while private providers offered a variety of immunisation options. They turned to their parliamentary representatives to put pressure on the Health Minister. In August and September 1989, six schools in the Ngaruawahia district approached Whetu Tirikatene Sullivan, MP for Southern Maori, to lobby Clark for free blood testing and immunisation for Maori children. Huntly and Hamilton schools asked Rob Storey, National MP for Waikato, to advocate for the protection of Maori children, and Simon Upton, National MP for Raglan, and Ian McLean, National MP for Tarawera, put questions to Clark in the House on behalf of their Maori constituents.<sup>151</sup>

Public health agencies also felt frustrated by the lack of clear direction from either the Minister of Health or the Department, while private vaccine schemes provided a range of uncoordinated services. In a letter to the Director-General of Health in September 1989, David Sloan, Medical Officer of Health for the Northland Area Health Board, complained that

this whole ‘messy’ business with SK&F [sic], the Whakatane Hepatitis unit and sundry GP initiatives is a result of a vacuum that I believe Wellington should have filled ... the credibility of the Dept/Ministry of Health regarding their commitment to public health measures is being called into question.<sup>152</sup>

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<sup>150</sup> M. Bassett, *Working with David: Inside the Lange Cabinet*, pp.507-9.

<sup>151</sup> Tirikatene-Sullivan to Minister of Health, 24 August 1989; Storey to Minister of Health, 6 September 1989, ABQU 632 W4452/703 131/171/4 66639, ANZW; NZPD, 7 September 1989, 501, p.12411; NZPD, Question for Oral Answer, 5 October 1989, ABQU 632 W4452/699 131/171/4 76902, ANZW.

<sup>152</sup> Sloan to DGH, ‘Hepatitis B Immunisation Programme in Schools’, 20 September 1989, ABQU 632 W4452 703 131/171/4 66639, ANZW.



In September 1989, as pressure mounted for an expansion of the immunisation policy, Clark made preparations to provide state-funded immunisation for school-aged children. In the latter part of 1989, the price of hepatitis B vaccine had fallen dramatically to NZ\$6 per course, so that the Health Department considered it feasible to fund the immunisation benefit claimed by doctors as well as the cost of the vaccine.<sup>153</sup> Nevertheless, Clark was aware of the complex issues that had arisen as a result of the preschool campaign and the emergence of numerous private schemes offering immunisation services for school children. For advice on how to proceed, she turned to the CDCAC. In early October 1989, she asked the committee to consider a proposal to make hepatitis B immunisations available to all children up to 16 years of age, in the same way as other immunisations were available, through the family doctor.

The CDCAC supported Clark's suggestion, but added that there needed to be a back up for children who had no regular medical contact, and that in view of the distinct disparity in prevalence among different ethnic groups, consideration should be given to targeting high risk communities and groups.<sup>154</sup> Clark remained unwilling to embrace a policy that emphasised ethnic divisions, however. On 11 October 1989, in response to a question in the House from Roger McClay, National MP for Waikaremoana, on Milne's programme of pre-testing, she expressed the view that 'hepatitis B is a serious problem, and ... some children are particularly at risk ... [but] I do not think it is wise to be singling out people for screening or inoculation on the basis of their ethnicity'.<sup>155</sup>

In early November 1989, Clark submitted a proposal for expanding the hepatitis B immunisation programme to the Cabinet Social Equity Committee. Three weeks later, on 27 November 1989, she announced that free hepatitis B immunisation would be available to all children up to the age of sixteen years from 1 February 1990 on the same basis as

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<sup>153</sup> CDCAC minutes, 5 October 1989, Ministry of Health Archives, Wellington. The fall in price reflected both the cheaper recombinant manufacturing process, and competition between suppliers.

<sup>154</sup> *ibid.*

<sup>155</sup> NZPD, 11 October 1989, 502, p.13076.

other vaccines on the childhood schedule.<sup>156</sup> The expanded policy was generally well-received, but as anticipated, there was criticism from some quarters. Even though the policy made financial provision for additional immunisation initiatives in high prevalence areas, Alexander Milne and Chris Moyes were critical that it did not include pre-immunisation screening for children at high risk of hepatitis B virus infection.<sup>157</sup> Similarly, Maori organisations regarded the expanded policy as acceptable for a low risk population, but as inappropriate for children in high risk communities.<sup>158</sup>

While reductions in the price of hepatitis B vaccine were undoubtedly a factor in Clark's decision to expand the hepatitis B immunisation policy, persistent pressure from the public and from public health workers and politicians also influenced the policy making process. Clark was determined to deliver the expanded programme through the primary health system, rather than through privately-run vaccine schemes, or another mass immunisation campaign. As Chapter Eight will discuss, this was part of her wider strategy to implement changes in the public health sector, but it also reflected her commitment to ensuring universal access to core public health programmes.

## **Conclusion**

The preschool campaign was a promising opportunity to address the high prevalence of hepatitis B among New Zealand children. However, the short lead-in time, the inherent difficulties of reaching preschool children, the lack of Maori involvement during the planning process, and the challenge of delivering four doses of vaccine over a 12 month schedule, all contributed to lower than expected immunisation rates, especially among Maori children. From late 1988 onwards, a range of individuals and organisations argued that the immunisation programme should be expanded further, to all school-aged

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<sup>156</sup> Cabinet Social Equity Committee, SEQ (89) 181, 'Hepatitis B Immunisation Programme', 6 November 1989, ABQU 632 W4452/705 131/171/4 67517, ANZW; Minister of Health, News Release, 27 November 1989, 'Hepatitis B Immunisation Programme Extended', ZABVA1073 888c, ANZA; News Release, Department of Health, Hepatitis B Immunisation', 31 January 1990, ABQU 632 W4452/704 131/171/4 67391, ANZW. State-funded hepatitis B immunisation was also extended to the household contacts and sexual partners of hepatitis B carriers at this time.

<sup>157</sup> Milne to Chairman of the CDCAC, 5 February 1990, 'Blood testing of Polynesian children', ABQU 632 W4452/705 131/171/4 75858, ANZW.

<sup>158</sup> Department of Health, Internal Memo, Coordinator Hauora Maori to Patel, 4 July 1990, ABQU 632 W4452/705 131/171/4 69791, ANZW.

children. Alexander Milne, the most vocal and best known proponent of childhood immunisation, took every opportunity to promote policy change.

Between 1987 and 1989, the political, economic and social factors that shaped hepatitis B policy varied. While the price of the vaccine fell, the Fourth Labour Government entered a period of instability and ministerial change and new models were introduced to the health services. In December 1988, the Director-General of Health, George Salmond, agreed to a private initiative offering immunisation to school-aged children on a user-pays basis. His decision opened the way for further private ventures which in turn put increasing pressure on the Health Minister Helen Clark to find funds for an expansion of the immunisation programme.

In November 1989, by offering free immunisation to all New Zealand children in the context of the family medical practice, Clark hoped to bring hepatitis B into line with other vaccine-preventable diseases, and to put an end to privately run vaccine services. In addition, she anticipated that this move would defuse the debate over hepatitis B screening which had emerged alongside the issue of childhood immunisation, and which will be explored in the next chapter.



## **CHAPTER SEVEN**

### **HEPATITIS B SCREENING POLICY**

**1988–2002**

In 1988, while the hepatitis B immunisation programme for infants and preschoolers struggled to gain traction in Maori communities, Alexander Milne and Chris Moyes turned their attention to ‘high risk’ school children. As Chapter Six discussed, Milne and Moyes not only believed that these children should be immunised against hepatitis B, but that they should be screened before immunisation, to identify those who were hepatitis B carriers. Milne, a vocal screening proponent, argued that it would produce unequivocal health benefits for carriers and their families, and that a carrier register maintained by the Whakatane-based Hepatitis Research Unit (HRU) would ensure that carriers could be contacted as soon as a treatment for chronic hepatitis B became available. His forceful advocacy of screening and carrier follow up attracted widespread support from Maori, who held concerns for the hepatitis B carriers in their communities.

The Health Department took a sceptical view of the hepatitis B screening proposal. While health officials were aware that there were numerous unidentified carriers in New Zealand, they were not prepared to consider a screening programme without convincing evidence that there was effective treatment for identified carriers, and that the advantages of screening outweighed the potential for harm. The departmental position was consistent with the cautious approach to screening taken by health authorities in other western countries. From the late 1960s, when medical academics in the US, UK and Europe had first challenged the claims being made for the extensive health benefits of screening, there had been a gradual acceptance of the need for a systematic assessment of screening proposals before programmes were introduced.

This chapter will explore the conflict that developed between Milne and health officials as a result of his persistent efforts to promote a national programme of hepatitis B

screening. It will discuss the strategies used by Milne to advance the screening cause, and consider the effects of single-issue advocacy in determining the direction of health policy. The chapter will begin by locating Milne's controversial screening campaign in the context of the wider screening debate. It will then discuss his promotion of the potential benefits for carriers from treatment with the herb *Phyllanthus amarus*, and the part it played in gaining widespread Maori support for hepatitis B screening. The chapter will draw attention to the important influence of cultural beliefs and societal values in the development of screening policy. Maori politicians will be seen to take an increasingly important role in the promotion of a national screening programme, and finally, to be central to the policy making process.

### **A critical approach to screening**

Screening is a relatively new component of public health medicine. While routine screening of individual patients was advocated in the US from the early twentieth century, screening was not widely adopted as a preventive health measure until after World War Two, when new technology made large-scale programmes possible. At first, screening to detect early signs of disease appeared to have multiple health benefits, and most doctors believed that the use of screening tests would result in reduced health risks and better outcomes for their patients. From the 1940s onwards, in New Zealand and in other Western countries, the introduction of screening tests and programmes met with a largely positive response from the medical profession and the general public.

The benefits of population-based screening were first demonstrated by the use of mass miniature radiography in tuberculosis control programmes. In New Zealand, as in the US and UK, mass miniature X-ray campaigns got underway in the 1940s, and gained momentum in the 1950s. As Deborah Dunsford explained in her 2007 PhD thesis on the social history of tuberculosis in New Zealand from World War Two to the 1970s, 'mass miniature X-ray was regarded as one of the lynchpins in the campaigns of New Zealand and other developed countries to eradicate tuberculosis'.<sup>1</sup>

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<sup>1</sup> In the UK and US, mass mobile radiography was discontinued in the late 1950s as TB prevalence rates fell but in New Zealand Dunsford explained that mass screening remained an integral part of the Health

During the 1950s, the range of screening tests and programmes increased rapidly in response to their apparent health benefits, the opportunities presented by new technology, and as a result of advocacy by experts in specialist areas of medicine.<sup>2</sup> In 1957, the US Commission on Chronic Illness, established in 1949 by influential organisations such as the American Medical Association, recommended screening ‘for diabetes, glaucoma, and cancers of the mouth, skin, breast, and rectum’.<sup>3</sup> In their 2007 book *Screening: Evidence and Practice*, Dr Angela Raffle and Sir J. A. Muir Gray explained that British doctors were more reticent than their trans-Atlantic counterparts in adopting routine screening tests. Nevertheless, by the mid-1960s, screening for breast cancer, cervical cancer, deafness in childhood, diabetes, glaucoma, iron deficiency anaemia, and phenylketonuria in newborn babies was well-established in the UK.<sup>4</sup> New Zealand, like Australia, followed this trend.<sup>5</sup> Within a relatively short time, therefore, screening acquired a widespread reputation as a desirable public health intervention.

During the 1960s, however, medical academics and health officials in the UK and US began to examine the claims being made for the benefits of screening procedures. Their investigations, which raised serious doubts about the effectiveness of screening in reducing the burden of disease, questioned the wisdom of investing scarce health resources into screening programmes. Further, they revealed that in some instances screening had the potential to do more harm than good. The adverse effects of screening

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Department strategy for TB eradication until the mid-1970s. Such was the financial investment and confidence in the benefits of the programme that it only ended as a result of departmental cost-cutting. D. A. Dunsford, ‘Seeking the Prize of Eradication: A Social History of Tuberculosis in New Zealand from World War Two to the 1970s’, p.99; pp.156-9.

<sup>2</sup> National Advisory Committee on Health and Disability, ‘Screening to Improve Health in New Zealand: Criteria to assess screening programmes’, Wellington, 2003. For further discussion of the introduction of cervical screening in the UK, North America, and New Zealand, see L. Bryder, ‘Debates about cervical screening: an historical overview’, pp.284-7; R. Jones, N. Fitzgerald, ‘The development of cervical cytology and colposcopy in New Zealand: 50 years since the first cytology screening laboratory at National Women’s Hospital’, NZMJ, 117, 1206, 26 November 2004, <http://www.nzma.org.nz/journal/117-1206/1179/> (9 November 2009).

<sup>3</sup> The Commission on Chronic Illness, 1957, cited in A. Raffle and J. A. Muir Gray, *Screening: Evidence and Practice*, Oxford, 2007, p.11.

<sup>4</sup> *ibid.*, pp.9-10.

<sup>5</sup> For example, in New Zealand, several hospitals in large centres started testing newborn babies for phenylketonuria (the ‘Guthrie test’) in the mid-1960s, and a national testing centre was established in 1969. Similarly, South Australia and Victoria introduced the Guthrie test in the mid-1960s. Privacy Commissioner, ‘Guthrie Tests’, 2003, online, nd, available at: <http://www.privacy.org.nz/assets/Files/70989185.pdf> (8 November 2009).

ranged from fear and lingering uncertainty about health status to over-diagnosis and overtreatment of healthy individuals.<sup>6</sup> Not surprisingly, these findings, which challenged screening orthodoxy, met with some resistance from the medical profession.<sup>7</sup>

In the late 1960s, two landmark publications on screening initiated a gradual shift in medical thinking. In 1967, the influential Nuffield Provincial Hospitals Trust set up a working party to consider screening in the UK under the chairmanship of Thomas McKeown, Professor of Social History in Birmingham.<sup>8</sup> Of the ten existing or proposed screening activities examined by the group, six were judged to be ‘seriously deficient’. In a ‘collection of essays’ published in 1968, they concluded that ‘public funds can be, and it seems may already have been, diverted from fields of certain benefit to procedures which are not proved and possibly harmful’.<sup>9</sup>

A WHO monograph on screening, also published in 1968, proved particularly significant in the development of an evidence-based approach for the evaluation of screening proposals. The authors, Dr Max Wilson, a senior medical officer in the UK Ministry of Health, and Dr Gunner Jungner, a Swedish biochemist, warned of the difficulties of developing an effective and ethically sound screening programme. While they conceded that ‘in theory, screening is an admirable method of combating disease’, they cautioned that ‘in practice, there are snags’.<sup>10</sup>

In an attempt to guide the selection of suitable screening projects, Wilson and Jungner defined a set of ten criteria, based on the acceptability of the test to the population being screened, an assessment of the cost of screening and case-finding in relation to the total budget for medical care, and the availability of adequate and acceptable treatment for

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<sup>6</sup> W. H. Holland and S. Stewart, *Screening in Disease – What Works?*, Oxford, 2005, p.3; p.12.

<sup>7</sup> See for example, A. Raffle and J. A. Muir Gray, *Screening: Evidence and Practice*, pp.10-27, for a discussion of the optimistic claims made for cervical screening in the UK in the 1960s, and the uproar that arose as a result of criticism of the screening programme by medical academics in the late 1960s and 1970s.

<sup>8</sup> T. McKeown, *Screening in Medical Care; Reviewing the Evidence, a Collection of Essays*, cited in A. Raffle and J. A. Muir Gray, *Screening: Evidence and Practice*, p.11.

<sup>9</sup> *ibid.*, p.11.

<sup>10</sup> Preface to J. M.G. Wilson and G. Jungner, *Principles and Practice of Screening for Disease*, World Health Organization, Geneva, 1968.



those people found to have early or asymptomatic disease.<sup>11</sup> Wilson and Jungner put particular emphasis on the availability of treatment for the condition sought: ‘of all the criteria that a screening test should fulfil, the ability to treat the condition adequately, when discovered, is perhaps the most important. In adhering to the principle of avoiding harm to the patient at all costs ... treatment must be the first aim’.<sup>12</sup>

Their views had the support of leading figures in public health medicine. In the early 1970s, prominent UK epidemiologists Professor Archie Cochrane and Dr Walter Holland drew attention to the critical difference between the ethics of everyday medical practice and those of screening for disease:

If a patient asks a medical practitioner for help, he does the best he can. He is not responsible for defects in medical knowledge. If, however, the practitioner initiates screening procedures he is in a very different situation. He should, in our view, have conclusive evidence that screening can alter [in a positive way] the natural history of disease in a significant proportion of those screened.<sup>13</sup>

In the 1970s, Wilson and Junger’s criteria for evaluating screening proposals were widely adopted by health authorities and policy makers as the accepted standard for decision

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<sup>11</sup> Wilson and Jungner’s screening criteria were as follows: 1. The condition sought should be an important health problem; 2. There should be an accepted treatment for patients with recognized disease; 3. Facilities for diagnosis and treatment should be available; 4. There should be a recognizable latent or early symptomatic stage; 5. There should be a suitable test or examination; 6. The test should be acceptable to the population; 7. The natural history of the condition, should be adequately understood; 8. There should be an agreed policy on whom to treat as patients; 9. The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole; 10. Case-finding should be a continuing process and not a ‘once and for all’ project.

<sup>12</sup> *ibid.*, pp.27-8.

<sup>13</sup> A. L. Cochrane, W. W. Holland, ‘Validation of screening procedures’, *British Medical Bulletin*, 27, 1, 1971, p.3. The views expressed by Cochrane and Holland continued to be espoused by leading epidemiologists throughout the late 1970s and 1980s. Geoffrey Rose, for example, Professor of Epidemiology at the London School of Tropical Medicine and Hygiene, produced a celebrated series of articles for the *British Medical Journal* entitled ‘Epidemiology for the Uninitiated’, which alluded to the controversial aspects of screening, and discussed the need for doctors to be aware of their ‘special obligation to ensure that screening is beneficial’. G. Rose, D. J. P. Barker, ‘Screening’, *British Medical Journal*, 18 November 1978, pp.1417-8.

making on screening policy.<sup>14</sup> Nonetheless, this did not mean that all members of the medical profession accepted a more critical approach to screening, or that interest groups and individuals did not continue to advocate strongly for the introduction of screening programmes on the basis of new technology or the apparent benefits of a screening procedure. In their 2007 text, Raffle and Muir Gray included a brief but illuminating historical review of screening in the UK and US. They noted the ‘slow but important transition’ towards greater awareness of the theory and practice of screening from the late 1960s to the mid-1990s. During these years, they described screening as a controversial and conflict-ridden area of medicine.<sup>15</sup>

In New Zealand, the bitter struggle over the introduction of a hepatitis B screening programme during the 1990s exemplified the divisive nature of the screening debate. While Alexander Milne, Chris Moyes, and their supporters were firmly convinced that individual hepatitis B carriers would gain tangible benefits from diagnosis and surveillance, public health practitioners in the Health Department took a critical approach to assessing the overall benefits and harms of the screening proposal. Health officials were sceptical of the advantages of hepatitis B screening over a concerted campaign of infant immunisation, whereas Milne and Moyes were determined to address what they perceived as the needs of specific communities with high rates of hepatitis B carriage. Each side held sharply opposing views on the potential for screening to reduce the spread of infection, and to relieve the burden of suffering and disease among hepatitis B carriers.

The conflicting arguments over the introduction of a hepatitis B screening programme exposed the divergent ideas and expectations of screening held by health professionals and the wider community. A strong belief in the health benefits of screening that took root in the 1950s persisted over the following decades, despite the advice of medical

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<sup>14</sup> A. Andermann, I. Blancquaert, S. Beauchamp, V. Déry, ‘Revisiting Wilson and Jungner in the genomic age: a review of screening criteria over the past 40 years’, *Bulletin of the World Health Organization*, 86, 4, April 2008, pp.241-320, <http://www.who.int/bulletin/volumes/86/4/07-050112/en/index.html> (9 November 2009).

<sup>15</sup> A. Raffle and J. A. Muir Gray, *Screening: Evidence and Practice*, p.17.

academics and epidemiologists who stressed the need for careful consideration of the benefits and harms of screening before new programmes or procedures were introduced.

### **Gaining support for screening high-risk children**

Alexander Milne and Chris Moyes' initial interest in the carrier state was stimulated by their 'suspicion that the source of many of the acute hepatitis B infections in childhood was a pool of infective carriers in the young population'.<sup>16</sup> During the 1980s, when international researchers confirmed the long term risks of chronic hepatitis B virus infection, their focus shifted from youthful carriers as 'reservoirs of infection' to their prospects of developing serious liver disease in adulthood. In 1988, notwithstanding the introduction of universal hepatitis B immunisation for infants and preschool children, Milne and Moyes began to promote a programme of hepatitis B immunisation targeting 'high risk' school children, which included pre-immunisation screening to identify those children who were hepatitis B carriers. To gain support and credibility for this concept, they turned to their long time allies from within the country and overseas.

In February 1988, Milne approached Professor Eru Pomare, Dean of Medicine at the Wellington School of Medicine, for his views on a screening and immunisation programme for Maori school children at high risk of hepatitis B virus infection. Pomare had been a strong advocate of the work of the HRU since the mid-1980s, when, as Chapter Four discussed, he had undertaken a ministerial investigation into the Eastern Bay of Plenty immunisation programme. In his 1985 report, he had estimated that there were between 60,000 and 90,000 hepatitis B carriers in New Zealand, 'all ... potential victims for chronic and sometimes fatal liver disease'.<sup>17</sup> Despite Pomare's obvious concerns for carriers, however, he qualified his support for Milne's screening proposal.

Pomare was in favour of screening at risk school children, and of testing the mothers of the children found to be carriers, in an effort to identify those children who had been

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<sup>16</sup> C. D. Moyes, 'A National Programme to Control Hepatitis B in an Endemic Area', p.41.

<sup>17</sup> E. W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.57.

infected in infancy. He considered these children to be at particularly high risk of developing cirrhosis and liver cancer in later life. He recommended that, as adults, they should receive the benefit of medical follow up along the lines of the regular screening he offered hepatitis B carriers in his private gastroenterology practice: 'I have quite a number of adult carriers whom I see at 3 monthly intervals for liver ultrasound and serum alpha fetoprotein [a blood marker of liver cancer]. I have detected two early [liver tumours] to date, both of which were imminently respectable.'<sup>18</sup> Nevertheless, Pomare held concerns that a programme that prioritised Maori children would neglect the needs of Pakeha children in high risk areas, and that the proposal could lead to 'Maori people again being seen in a negative situation'. In correspondence with Milne, Pomare suggested two ways to approach pre-immunisation screening:

A Maori-orchestrated programme could be set up and perhaps run on tribal lines. You would have an important role to play as an adviser ... and the second possibility ... would be to go for a study in 'higher risk' areas. You could ... choose such areas as being those with a Maori population of say, more than 15 to 20% ... The main advantage of this sort of approach would be to forestall objections that this was a racially selective programme ...<sup>19</sup>

Pomare saw benefits in pre-immunisation screening, not only to ensure carriers were aware of their health status, but also to avoid a 'false sense of security' that they were immune against hepatitis B.<sup>20</sup> His assiduous approach to carrier follow up made a strong impression on Milne, who later argued that all carriers, not only the private patients of medical specialists should be regularly reviewed in adulthood, when the risk of developing liver cancer increased.<sup>21</sup> Pomare's suggestion that Milne act as an adviser to autonomous Maori screening projects appeared to have less appeal, however; he and

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<sup>18</sup> Pomare to Milne, 23 February 1988, ABQU 632 W4452 702 131/171/ 64449, ANZW.

<sup>19</sup> *ibid.*

<sup>20</sup> *ibid.*

<sup>21</sup> A. Milne, 'The Plight of Hepatitis B Carriers in New Zealand', Submission to the Maori Affairs Committee, 26 July 1995, Report of the Maori Affairs Committee, *Report of the Maori Affairs Committee: Hepatitis B Screening Programme for Maori*, Wellington, 1995, p.20. In the late 1980s, family doctors did not provide follow up for hepatitis B carriers; if they considered that a carrier required medical follow up they would refer the patient to a specialist gastroenterologist.

Moyes were already convinced of the need for a centralised carrier screening and surveillance programme coordinated by the HRU in Whakatane.

In mid-1988, Milne and Moyes travelled to Alaska to meet with Dr Brian McMahon, the leader of the Alaska Native Medical Service hepatitis B programme. The trip to Alaska, which was funded by the New Zealand Medical Research Council (MRC), gave Milne and Moyes the opportunity to study the screening, immunisation and surveillance programme for indigenous Alaskans. Milne had specific expectations of the visit: 'we were preparing ourselves for a job which we assumed would be accepted by the NZ health authorities as necessary because of the personal health/public health implications of this serious virus'.<sup>22</sup>

On their return to New Zealand, Milne and Moyes made plans to promote hepatitis B screening by holding a workshop in Whakatane to discuss 'carrier management'. Milne sought financial support from the Health Department towards the costs of the workshop, but was turned down on the grounds of financial constraints.<sup>23</sup> All available funding was committed to the expanded hepatitis B immunisation programme, and in mid-1988, Dr John Stephenson, Manager of the Health Protection Programme, was dealing with issues of more immediate concern. As the previous chapter discussed, preliminary data from the hepatitis B preschool campaign indicated that immunisation coverage was significantly lower than the Health Department had anticipated.<sup>24</sup>

The HRU workshop on carrier management was held in Whakatane in October 1988. It was attended by a small group of overseas experts in viral hepatitis and liver disease, all of whom were supporters of hepatitis B screening and regular follow up surveillance of adult carriers.<sup>25</sup> Discussion at the workshop centred on issues that were to dominate the

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<sup>22</sup> *ibid.*, p.13.

<sup>23</sup> Stephenson to Milne, 'Proposed Workshop – Management of the Hepatitis B Carrier', 24 June 1988, ABQU 632 W4452 702 131/171/4 64448, ANZW.

<sup>24</sup> Ashworth to Health Development Units, 10 June 1988, ABQU 632 W4452 702 131/171/4 64448.

<sup>25</sup> These were: Dr Thomas London from the Fox Chase Cancer Center, Philadelphia, Dr Elizabeth Fagan from the Liver Unit, King's College, London, Dr Ron Lucas, Infectious Diseases Specialist, and Dr Stephen Locarnini, microbiologist, from Fairfield Infectious Diseases Hospital, Melbourne. HRU,

hepatitis B screening debate throughout the 1990s: the benefits of screening to identify carriers, counselling and education services for carriers, community support for hepatitis B screening, and regular medical follow up of carriers to detect liver disease.<sup>26</sup> During the workshop, Milne introduced a proposal for screening ‘high risk’ primary school children and establishing a register of those identified as carriers ‘to facilitate surveillance and treatment as it became available’. According to the summary of proceedings, this ‘proposal was generally, though not universally, viewed favourably’. While most medical participants were in favour of Milne’s plan to establish a carrier register and the provision of regular medical checks for hepatitis B carriers, a minority regarded large-scale carrier follow up as ‘too daunting’, or ‘barely justified’ because of the lack of effective treatment for the carrier state.<sup>27</sup>

After the workshop, Dr Keith Ridings, the Medical Superintendent of Whakatane Hospital, sent Dr George Salmond, the Director-General of Health, his personal perspective of events. Ridings expressed his support for hepatitis B screening and for a centralised carrier register held by the HRU. He was also in favour of regular carrier follow up with alpha fetoprotein testing and ultrasound scans. On the matter of Milne’s proposal to screen high risk school children, however, Ridings demurred. Until August 1988, he had, in effect, been Milne’s employer. The Bay of Plenty Hospital Board had provided half Milne’s salary and premises for the HRU laboratory on the Whakatane Hospital site, while the rest of his salary had been covered by the MRC. When substantial cuts were made to hospital board allocations in mid-1988, the Board ended Milne’s employment.<sup>28</sup> Ridings suggested to Salmond that Milne had additional reasons for his proposal to screen high risk areas and high risk populations for hepatitis B carriers: ‘I know that Sandy [Milne] is trying to produce future [laboratory] work to keep

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‘Management of the Hepatitis B Carrier in New Zealand, Summary of the proceedings of a workshop held in Whakatane on 6 October 1988’, ABGX 16127 W5189 Bx53 MA 4/4/2, ANZW.

<sup>26</sup> *ibid.*

<sup>27</sup> *ibid.*

<sup>28</sup> Ridings to DGH, ‘Alexander Milne – Whakatane Hepatitis B Research Unit’, 30 August 1988, ABQU 632 W4452/703 131/171/4 65315, ANZW. In 1988, Milne was engaged in studies evaluating the effectiveness of the low dose programme, and in December 1988, the Health Department agreed to meet half of Milne’s salary for ten months, until mid-October 1989, when his research grants from the MRC would also end. Stephenson to Minister of Health, 3 March 1989, ABQU 632 W4452/703 131/171/4 65315, ANZW.

himself busy.’ He ended on a prescient note; ‘I think the subject [of carriers] will crop up again.’<sup>29</sup>

Ridings soon proved correct. In January 1989, Moyes sent Nigel Ashworth, coordinator of the National Hepatitis B Immunisation Programme, a discussion document of a ‘very preliminary’ proposal to establish a confidential carrier register and a carrier screening and surveillance programme. During 1988, Ashworth had become an enthusiastic supporter of Milne and Moyes’ broader vision for hepatitis B control, and as a health official, had advocated on their behalf for funding for immunisation projects in the Pacific and for research facilities in Whakatane.<sup>30</sup> Moyes asked Ashworth ‘whether you feel it would be possible for the Department to be involved in the general co-ordination and encouragement of such a scheme ... [as] without [departmental] backing there is no way we’d get co-operation from all concerned or the access to medical records’.<sup>31</sup> Moyes noted that Brian McMahon was prepared to act as an adviser on the proposal, while Eru Pomare had agreed to act as a co-investigator with Neil Pearce, the biostatistician who had worked on the 1984 Kawerau study.<sup>32</sup>

There is no evidence to suggest that Ashworth responded to Moyes’ request.<sup>33</sup> He resigned from the Health Department in late February 1989, and the implementation of the preschool immunisation programme continued to absorb the limited focus, funding

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<sup>29</sup> Ridings to DGH, 26 October 1988, ABQU W4452/699 131/171/1, ANZW.

<sup>30</sup> Ashworth to Richards, 27 July 1988, private papers. N. Ashworth.

<sup>31</sup> Moyes to Ashworth, 19 January 1989, private papers. N. Ashworth.

<sup>32</sup> In the interim Pearce had co-authored numerous papers with Milne, Moyes, and others on hepatitis B prevention and control. See for example, A. Milne, G. K. Allwood, N. E. Pearce, C. R. Lucas, S. Krugman, ‘Low dose hepatitis B vaccination in children’ (1986); A. Milne, M. Dimitrakakis, C. Campbell, C. R. Lucas, G. K. Allwood, P. Goldwater, N. E. Pearce, Saul Krugman, ‘Low-dose vaccination against hepatitis B in children: One-year follow-up’ (1987); A. Milne, G. K. Allwood, C. D. Moyes, N. E. Pearce, K. Newell, ‘A seroepidemiological study of the prevalence of hepatitis B infections in a hyperendemic New Zealand community’ (1987); Milne, A., C. D. Moyes, G. K. Allwood, N. E. Pearce, S. Krugman, ‘Antibody responses to recombinant, yeast-derived hepatitis B vaccine in teenage New Zealand children’, NZMJ, 101, 24 February 1988, pp.67-9.

<sup>33</sup> In December 1990, in correspondence with the then Health Minister, Simon Upton, Moyes claimed that he had put this proposal to the Health Department twice in early 1989, with no response. Moyes to Minister of Health, ‘Hepatitis B Programmes in Schools’, 30 October 1990, ABQU 632 W4452/698 131/171/1 70059, ANZW.

and energies available for hepatitis B control.<sup>34</sup> In addition, as discussed in Chapter Six, in early 1989 senior health officials were awaiting ministerial direction on the proposal to introduce user pays hepatitis B immunisation for school children, which was among the first issues to be addressed by the newly appointed Health Minister Helen Clark.

It is clear then, that Milne and Moyes gained their initial support for a screening programme from interested individuals within the local and international research community. While senior health officials accepted the existence of the carrier problem, they neither viewed the screening proposal as a pressing priority nor as a plausible policy objective, particularly in the midst of a mass hepatitis B immunisation campaign.

### **The promise of phyllanthus**

Soon after Helen Clark assumed the role of Health Minister in early 1989, Milne wrote to inform her of the achievements and activities of the HRU.<sup>35</sup> He drew particular attention to his plans for a New Zealand trial of a low cost herbal medicine derived from *Phyllanthus amarus*. In Milne's opinion, extracts of phyllanthus held the promise of a cheap, effective treatment for chronic hepatitis B virus infection, which, if realised, would provide a powerful incentive for the development of a hepatitis B screening programme.<sup>36</sup>

In the mid-1960s, researchers in the US and India began investigating the possible use of *Phyllanthus amarus* as an 'anti-hepatitis' medication. The plant was well known in India as an Ayurvedic medication for jaundice, and scientific studies undertaken in the 1980s suggested that it had potential as a means of eliminating the hepatitis B virus from the blood of carriers. In October 1988, a report published in the *Lancet* gave rise to hopes that phyllanthus would prove to be an effective treatment for chronic hepatitis B virus infection. The main author, Professor S. P. Thyagarajan of the Institute of Basic Medical

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<sup>34</sup> The preschool campaign, which began at the end of February 1988, was based on a four dose schedule of low dose plasma-derived vaccine over 12 months. Many health districts got off to a late start, so that immunisation clinics for the fourth dose of vaccine were still being held in April 1989.

<sup>35</sup> Helen Clark was Minister of Health from 30 January 1989 to 2 November 1990.

<sup>36</sup> Patel to Thompson, 'Hepatitis B', 4 April 1989, ABQU 632 W4452/703 131/171/4 66639, ANZW.



Science, Madras, had a number of co-investigators, including Baruch Blumberg, the recipient of the 1976 Nobel Prize in Medicine for the discovery of the hepatitis B virus.<sup>37</sup> Encouraged by Blumberg's involvement in the Madras study, Milne began planning a phyllanthus trial on New Zealand hepatitis B carriers to verify its therapeutic effects.<sup>38</sup>

At the beginning of February 1989, Milne wrote to inform Clark of the work of the HRU, and its proposal to 'examine affordable strategies for the treatment of the 50,000–80,000 carriers in New Zealand ... [based on] formal trials of a plant extract which has been found to be remarkably successful in India'.<sup>39</sup> He related the phyllanthus trials to a 'giant' survey the HRU was arranging to screen high risk primary school children: 'those ... found to be carriers will be offered surveillance [in the form of regular blood tests and ultrasound scans] and ... subsequently, treatment'. In addition, Milne bluntly stated that, 'New Zealand should have a hepatitis B control centre. It should be right here [in Whakatane] where the carriers have been identified and where most of the research is done.'<sup>40</sup>

Clark was non-committal in her reply to Milne, offering general encouragement for his concerns for hepatitis B carriers.<sup>41</sup> Nonetheless, his assertive approach to lobbying and expansive vision for the HRU troubled her, and she asked her senior advisers to clarify Milne's relationship with the Health Department.<sup>42</sup> In early March 1989, in correspondence with George Salmond, Director-General of Health, Clark expressed her

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<sup>37</sup> S. P. Thyagarajan, S. Subramanian, T. Thirunalasundari, P. S. Venkateswaran, B. S. Blumberg, 'Effect of *Phyllanthus amarus* on chronic carriers of hepatitis B virus', *Lancet*, 332, 8614, 1 October 1988, pp.764-6.

<sup>38</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.63.

<sup>39</sup> Milne to Minister of Health, 'Hepatitis B Control Centre', 1 February 1989, ABQU 632 W4452/703 131/171/4 65315, ANZW.

<sup>40</sup> *ibid.*

<sup>41</sup> This was reported later by Salmond, in a brief to his departmental staff in late August 1989. 'Brief for Proposed Meeting with Sandy Milne', 30 August 1989, ABQU 632 W4452 131/171/1, ANZW.

<sup>42</sup> Department of Health Memorandum, Stephenson to Minister of Health, 'Relationship A Milne/ Department of Health', 3 March 1989, ABQU 632 W4452/703 131/171/4 65315, ANZW. Clark later made notes on a letter from Milne to Dr Arvind Patel, Manager of the Communicable Diseases Unit, to the effect that his approach was 'obsessive', and the 'The Dept should not be harassed in this way'. Milne to Patel, 23 July 1990, ABQU 632 W4452 705 131/171/4 69791, ANZW.

intention to keep ‘on track’ with hepatitis B policy, by completing the preschool programme.<sup>43</sup>

Milne was undeterred by the Minister’s lukewarm response to his proposal for a Whakatane-based hepatitis B ‘control centre’. He operated on a broad front, keeping a wide range of research studies, immunisation projects and lobbying activities ‘on the go’ at the same time. In the short term, as discussed in Chapter Six, he was intent on gathering support from the Maori community for his proposal to screen and immunise Maori school children in the so-called ‘high risk’ health districts: Northland, Auckland, South Auckland, Waikato, Gisborne and Napier. In early March 1989, he and Moyes met with Sir Graham Latimer, Chairman of the New Zealand Maori Council, and representatives from the Department of Health, the Department of Maori Affairs, and the Maori Women’s Welfare League, to discuss plans for the project.<sup>44</sup>

Phyllanthus therapy was a key component of Milne’s screening proposal. The prospect of an effective treatment eclipsed the other more modest benefits of screening, which included the immunisation of susceptible contacts of identified carriers, and the provision of education and counselling. This was particularly so for child carriers, who would not benefit from a programme of regular surveillance to detect the onset of liver disease until they reached adulthood. Nevertheless, the suggestion that phyllanthus might provide a low cost, locally grown treatment for hepatitis B attracted widespread interest from Maori, in the anticipation that screening and a centralised carrier register would enable carriers to be contacted for treatment when it became available.

In discussions between Clark and senior health officials in July 1989, consideration was given to allocating funding for screening high risk primary school children before offering immunisation to those susceptible to the hepatitis B virus. This proposal was turned down on the advice of the CDCAC, which reiterated that the main objective of the

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<sup>43</sup> Minister of Health to Salmond, ‘Hepatitis B Immunisation Programme’, 9 March 1989, ABQU 632 W4452/703 131/171/4 65315, ANZW.

<sup>44</sup> A. Milne, ‘Hepatitis B control in high risk primary schoolers’, Record of a meeting held in the Department of Maori Affairs, 1 March 1989, ABQU 632 W4452/703 131/171/4 75858.

national immunisation programme was to protect infants and young children against hepatitis B. Not only did the CDCAC consider there was no risk in immunising children that had previously been infected by the virus, but from a practical perspective, screening would expose children to an additional procedure before beginning a course of hepatitis B vaccine.<sup>45</sup> In further considerations, the CDCAC also proposed that the lack of an effective treatment for chronic hepatitis B virus infection was an ethical reason for rejecting the introduction of mass screening prior to hepatitis B immunisation.<sup>46</sup>

In September 1989, the HRU held a workshop in Whakatane to discuss the use of phyllanthus as a treatment for hepatitis B carriers. The meeting, which was sponsored by the MRC, the HRU, and the Eastern Bay of Plenty Hepatitis B Immunisation Trust, was attended by thirty doctors, medical scientists and health officials from New Zealand, Australia, Vanuatu, Japan, the US, UK, and India.<sup>47</sup> Dr John Stephenson, Manager of the Health Protection Programme, and Dr Ron Lucas, Head of Medicine at Fairfield Infectious Diseases Hospital, Melbourne, acted as co-chairmen of the proceedings.<sup>48</sup>

Both Stephenson and Lucas were sympathetic to Milne's goal of developing an effective treatment for chronic hepatitis B carriage. Nevertheless, they both expressed concerns about his plans to conduct a phyllanthus trial on New Zealand hepatitis B carriers. Stephenson urged caution, requesting more information on its side-effects, dosages and the duration of phyllanthus therapy.<sup>49</sup> Lucas had been closely involved in hepatitis B research with Milne and Moyes since the early 1980s; yet he too was wary of the lack of scientific data on the safety and efficacy of phyllanthus. Lucas suggested that a small study be considered, with two to three years set aside for the necessary planning and preparation before research began.<sup>50</sup> Despite these concerns, however, Milne would not contemplate delaying the phyllanthus study. From his perspective, not only was the safety

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<sup>45</sup> Minutes of the CDCAC, 6 April 1989, Ministry of Health Archives, Wellington.

<sup>46</sup> CDCAC minutes, 5 October 1989, Ministry of Health Archives, Wellington.

<sup>47</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.61.

<sup>48</sup> Professor Thyagarajan, the main author of the 1988 article on Phyllanthus treatment was among the workshop participants. 'Report of the Meeting on the Use of Phyllanthus Amarus in Hepatitis B Infection', 14-15 September 1989, Whakatane, private papers, N. Ashworth.

<sup>49</sup> *ibid.*

<sup>50</sup> *ibid.*

and effectiveness of phyllanthus already proven, but the promise of phyllanthus treatment had become a central feature of his screening campaign. Shortly after the workshop, the HRU began cultivating phyllanthus in Whakatane in preparation for a collaborative trial with researchers from Japan, Egypt, Burma, Singapore and Vanuatu.<sup>51</sup>

In early 1990, Milne promoted the benefits of phyllanthus therapy at every opportunity. On 1 February 1990, hepatitis B immunisation was expanded to all New Zealand children up to sixteen years of age; however, as Chapter Six discussed, pre-immunisation screening was not included in the new policy. In correspondence with Dr Stewart Reid, Chairman of the CDCAC, Milne argued that the expanded programme was ‘bad for Maori and Pacific Island children’, asserting that ‘Professor Eru Pomare has ... advised Maori not to have vaccine without prior blood tests’. He added that the HRU had just harvested their first crop of phyllanthus, and that ‘if our trials are successful we will be scaling up from our current 10,000 plants to over 100,000 ... we will have treatment available in 12 months time (not 5-7 years) and trials in children are planned’.<sup>52</sup>

Milne’s extravagant claims for phyllanthus attracted the attention of the television media. A TVNZ ‘Frontline’ documentary on hepatitis B, screened in April 1990, featured his plans to grow and harvest phyllanthus to treat hepatitis B carriers.<sup>53</sup> The presenter, Rob Harley, told viewers that ‘the Health Department supports a vaccination programme but Sandy Milne and others have good reasons for wanting mass screening particularly as a cure may be just around the corner’. In an interview with Clark, Harley challenged her decision to expand the hepatitis B immunisation programme without the addition of pre-immunisation screening. Clark, in turn, questioned Milne’s enthusiastic promotion of phyllanthus and reaffirmed her stance on hepatitis B control: ‘identifying carriers does not mean they can be treated ... I do not think that a cure is just around the corner ... the most legitimate objective [of Government policy] is to stop the spread of the disease’.<sup>54</sup>

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<sup>51</sup> *ibid.*

<sup>52</sup> Milne to Reid, ‘Blood Testing of Polynesian children’, 5 February 1990, ABQU 632 W4452/703 131/171/4 75858, ANZW.

<sup>53</sup> Frontline, ‘The Quiet Killer’, 15 April 1990, P95719, TVNZ Archives.

<sup>54</sup> *ibid.*

In mid-1990, Milne recruited 105 hepatitis B carriers for a three month trial of phyllanthus therapy. When the first crop of Whakatane-grown phyllanthus proved too small for his needs, he amalgamated it with phyllanthus from Vanuatu and Fiji where the plant grew readily in the tropical conditions.<sup>55</sup> Milne stopped the trial after two months, however, when it failed to confirm the results of the 1988 Madras study. The disappointing outcome was reported in an article in the *New Zealand Medical Journal* four years later; in the meantime, Milne and Moyes continued to allude to the potential benefits of ‘traditional herbal remedies for liver disorders’.<sup>56</sup> They appeared reluctant to let go of the promise of phyllanthus; in their 1994 article they maintained that the New Zealand trial did not ‘necessarily prove that the raw, dried, milled plant is ineffective ... only that our extract of *P. amarus* had no effect when given to New Zealand carriers’.<sup>57</sup>

The unsuccessful trial did little to discourage Milne and Moyes’ drive to establish a screening programme. When phyllanthus failed to fulfil its potential as an antiviral remedy it was quietly shelved, and the emphasis of their screening campaign was redirected towards the broader benefits of screening for carriers and their families.

### **Maori take a strong role in the screening debate**

The screening debate became increasingly heated in 1990, when leading Maori politicians and health professionals joined Alexander Milne’s campaign for pre-immunisation screening in high-risk communities. While the Health Department and the CDCAC were unwilling to consider such a programme, they were sensitive to criticism that the preschool immunisation campaign had failed to achieve adequate coverage of Maori children, and to accusations of neglecting an important Maori health issue.

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<sup>55</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.63.

<sup>56</sup> C. D. Moyes, ed., *Management of Hepatitis B Carriers: A Guide for Health Professionals*, Hepatitis Research Unit, Whakatane, 1991, p.9.

<sup>57</sup> A. Milne, N. Hopkirk, C. R. Lucas, J. Waldon, Y. Foo, ‘Failure of New Zealand carriers to respond to *Phyllanthus amarus*’, *NZMJ*, 107, 22 June 1994, p.243.

In 1990, four main groups emerged in the hepatitis B screening debate: the Health Department, the CDCAC, the Advisory Committee on Maori Health, and the HRU.<sup>58</sup> While the Advisory Committee on Maori Health and the HRU shared a common belief in the benefits of screening, the CDCAC and Health Department saw few, if any, advantages in population-based screening to identify hepatitis B carriers. In response to the arguments put forward by Milne and prominent members of the Maori community, the CDCAC approached Dr Don Bandaranayake, Dr Nicholas Wilson and Dr Judith Miller, public health physicians at the New Zealand Communicable Disease Centre, to prepare a discussion paper on the pros and cons of screening prior to hepatitis B immunisation.<sup>59</sup>

From a public health standpoint, the major advantage of hepatitis B screening was the opportunity it provided to immunise the close contacts of carriers. For carriers themselves, Bandaranayake, Wilson and Miller concluded that the potential for harmful effects from screening, such as stigmatisation, was greater than the benefits they were likely to receive. Counselling for carriers was seen as unlikely to be of widespread assistance, given that ‘these services are currently poorly provided and [financial and geographical] barriers of access are likely to exist for Maori and individuals from lower socio-economic groups’. Furthermore, they regarded individual counselling sessions to change health-related behaviour as less likely to succeed than broad-based education programmes, such as the 1988 Health Department ‘safer sex’ campaign, which were considered more effective in encouraging lifestyle change.<sup>60</sup>

On the critical issue of treatment for carriers identified through a screening programme, Bandaranayake, Wilson and Miller concluded that interferon, the only available antiviral

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<sup>58</sup> Helen Clark appointed the Ministerial Advisory Committee on Maori Health in early 1989. ‘Like its predecessor [the Standing Committee on Maori Health which was dissolved in 1988] it provided some focus for Maori policy development within the Health Department even though its major role was to provide advice to the Minister of Health’. M. Durie, *Whaiora: Maori Health Development*, p.106.

<sup>59</sup> The NZCDC, formerly the National Health Institute, was established in 1990 as a government funded research centre for communicable disease.

<sup>60</sup> N. Wilson, J. Miller, D. Bandaranayake, ‘Discussion Paper for the Communicable Disease Control Advisory Committee: Issues Concerning Screening in the Context of a Hepatitis B Immunisation Campaign’, 4 July 1990, ABQU 632 W4452/699 131/171/1 76900, ANZW, pp.5-6.

therapy, would be of limited benefit for most carriers. Its high cost and significant side effects ruled it out for general use, and only certain carriers were considered suitable candidates for the drug. As for phyllanthus therapy, they deemed the ethics of screening on the presumption of a future treatment ‘questionable’. They pointed to the major costs of ‘keeping track of carriers for years until a new treatment becomes available’, and the ‘extreme difficulties [of] keeping track of the whereabouts of many young people once they had left school’. Moreover, after reviewing the available data on the regular follow up of identified carriers with alpha fetoprotein tests and liver ultrasound to detect the development of liver cancer, they determined that this was likely to be of limited value.<sup>61</sup>

Overall, the three physicians argued for retaining the status quo, recommending that the CDCAC maintain its stance against pre-immunisation screening until further debate or consultation suggested that a change was appropriate. From an evidence-based perspective, ‘the benefits of pre-immunisation screening did not clearly outweigh the risks’. Nonetheless, in recognition of the social and cultural aspects of the screening proposal, they also acknowledged the need for further consultation with Maori, ‘to help define the [screening] issues in a broader framework’.<sup>62</sup>

To gain his input on the screening issue, Dr Stewart Reid, Chairman of the CDCAC, invited Professor Eru Pomare to join the committee at their July 1990 meeting. Pomare was unable to attend, but he recommended that the CDCAC should ‘seriously consider’ screening high risk children before immunisation and take into account the need for a ‘good’ education programme about hepatitis B, because there was ‘a great deal of concern within the Maori community about hepatitis B’. Further, he argued that ‘area health boards and Iwi authorities should have a major responsibility in resourcing [sic] hepatitis B programmes to the high risk Maori and Polynesian communities, and more discussion with [these] communities should take place’.<sup>63</sup>

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<sup>61</sup> *ibid.*, pp.8-9.

<sup>62</sup> *ibid.*, p.3.

<sup>63</sup> Pomare to Reid, ‘Hepatitis B Immunisation’, 5 July 1990, ABQU 632 W4452/705 131/171/4 69791, ANZW.

The Minister of Maori Affairs, Koro Wetere, and the Ministerial Committee on Maori Health endorsed Pomare's views.<sup>64</sup> In a draft policy paper presented to the CDCAC at their July 1990 meeting, the Committee on Maori Health recommended that the hepatitis B control programme be expanded to include screening for *all* members of high risk communities, and that education and counselling be provided for carriers. It proposed that a community-based approach be used to deliver screening, immunisation and education services to high risk communities. The paper stressed the need for a 'dual strategy more appropriate for the New Zealand population', in which those at low risk of infection received immunisation without pre-screening, while members of high risk communities were pre-screened to identify carriers. In addition, Wetere proposed that a national coordinator based in the Maori Health Unit of the Department of Health be appointed to oversee the implementation of the screening and immunisation programme.<sup>65</sup>

In correspondence with Helen Clark in August 1990, Reid informed her of the strong representations by Maori, observing that while the infant immunisation programme remained the 'cornerstone of long-term hepatitis B control ... "focused" campaigns in high risk communities [we]re clearly justified'. The CDCAC recommended that the Minister provide resources for communities to conduct their own immunisation campaigns, and that 'if those communities decide that pre-testing should be an integral part of their campaign [then] ... it should be included'.<sup>66</sup>

A general election was pending, and Clark had little time to respond to the CDCAC's advice. In late October 1990, the Labour Party was defeated at the polls, and Simon Upton was appointed Minister of Health in the National Cabinet. Chris Moyes immediately wrote to Upton in support of Milne's programme of blood testing Maori and

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<sup>64</sup> Wetere to Minister of Health, 'Hepatitis B Immunisation Programme', 6 July 1990, ABQU 632 W4452/707 131/171/4 69791, ANZW. The Maori Health Policy Unit, Te Wananga Hauora Maori, was established in 1990 to provide policy advice, information, and advisory services to the Health Department and area health boards. M. Durie, *Whaiora: Maori Health Development*, p.106.

<sup>65</sup> *ibid.*

<sup>66</sup> Reid to Clark, 12 August 1990, ABQU 632 W4452/707 131/171/4 69791, ANZW.



Pacific school children.<sup>67</sup> He went straight to the heart of the matter: 'it is sometimes stated that there is no point in identifying carriers as there is no curative treatment. This argument is not valid'. Moyes informed Upton that the opportunity to immunise the contacts of carriers, to provide lifestyle advice and regular surveillance to detect the onset of chronic liver disease and liver cancer were equally important reasons for implementing a screening programme. Moreover, Moyes declared that 'Maori people clearly wish the [school-based] blood testing programme to be supported'.<sup>68</sup>

Upton was receptive to Milne's proposal for school-based screening for high-risk children. However, he appeared to pay little attention to the CDCAC's recommendation that high risk communities should be equipped to develop their own programmes. In November 1990, Upton met with Milne and Health Department staff, and in early 1991, following a review of the 'unresolved' issues of hepatitis B screening by the Health Department, he agreed to fund a contract with the Hepatitis Control Trust (HCT), of which Milne was the director, for a screening and immunisation programme for children in high risk health areas.<sup>69</sup>

Hence, in 1990, Maori provided the critical leverage for a change to hepatitis B policy. The decision to fund a targeted screening programme was not based on scientific research; rather it was a response to the strong expression of concern by Maori that the Health Department had so far failed to deliver appropriate immunisation services to Maori children. Nevertheless, when the school-based screening programme was implemented, it was under the direction of Milne, who had drawn Maori into the screening debate, not under the leadership of autonomous Maori health services.

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<sup>67</sup> Moyes to Minister of Health, 'Hepatitis B Programmes in Schools', 30 October 1990, ABQU 632 W4452/698 131/171/1 70059, ANZW.

<sup>68</sup> Moyes to Minister of Health, 'Hepatitis B Programmes in Schools', 30 October 1990, ABQU 632 W4452/698 131/171/1 70059, ANZW.

<sup>69</sup> The Hepatitis Research Unit became the Hepatitis Control Trust in 1991, to undertake immunisation contracts with the National Government. V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.11; Johns to Minister of Health, 'Hepatitis B Policy Review', 19 December 1990, ABQU 632 W4452/698 131/171/1 70059, ANZW; Johns to Minister of Health, 'Contract with Hepatitis Control Trust', 15 February 1991, ABQU 632 W4452/706 131/171/4 74976, ANZW.

### **A consensus hui on screening**

Following the publication of screening guidelines for hepatitis B carriers by the HRU in late 1991, Alexander Milne attempted to win support for the introduction of opportunistic screening of Maori and Pacific adults for hepatitis B and a range of other health-related conditions in Whakatane and South Auckland.<sup>70</sup> While his proposal appeared to promote health gains for Maori in particular, it raised a range of technical, ethical and health resource issues that were the impetus for wider discussion and debate.

In early 1992, Milne began to lobby for the introduction of opportunistic ‘multi-factorial’ screening programmes for adults in areas of high hepatitis B prevalence.<sup>71</sup> Milne believed that his expertise in screening, developed as a result of the HRU’s school-based programme for high-risk children, would have positive spin-offs for Maori health providers in terms of encouraging ‘a turnaround in Maori health’.<sup>72</sup> While some doctors were convinced that Milne had an important role to play in improving the standard of Maori health, others, including senior specialists involved in diabetes care in South Auckland, reacted negatively to Milne’s proposal, pointing to the lack of established services to cope with a sudden influx of newly diagnosed cases.<sup>73</sup>

In late 1992, to resolve these and other screening issues, Te Puni Kokiri (the Ministry of Maori Development) invited the Health Research Council’s Maori Health Committee to convene a screening hui in Wellington chaired by Professor Eru Pomare.<sup>74</sup> Pomare was

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<sup>70</sup> The HRU, of which Milne was the director, instigated the development of guidelines for the management of individual hepatitis B carriers in 1991, which were endorsed by the Health Department. C.D. Moyes, *Management of Hepatitis B Carriers: A Guide for Health Professionals*, p.1.

<sup>71</sup> Milne proposed screening for diabetes, hepatitis B, as well as serum lipids and uric acid, but envisaged that other screening tests could be included to save money and increase the health benefits for Maori and Pacific peoples. V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, pp.87-91; Te Manawa Hauora, *Hui Whakamaarama: Report of a Consensus Hui Concerning Screening Amongst Maori*, Wellington, 1993, p.6; pp.10-1.

<sup>72</sup> At the Hui Whakamaarama, Milne expressed the view that ‘screening was only a tiny part of the whole deal’ and that Maori health workers will ‘try to change attitudes towards health ... You’re better at that than me, but there’s one thing I’m better at than you, and that’s screening’. *Hui Whakamaarama: Report of a Consensus Hui Concerning Screening Amongst Maori*, p.11.

<sup>73</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.87.

<sup>74</sup> *ibid.*, pp. 90-1. Te Puni Kokiri, the Ministry of Maori Development, was established under the Ministry of Maori Development Act 1991, which effectively abolished the former Ministry of Maori Affairs (Manatu Maori) and the Iwi Transition Agency (Te Tira Ahu Iwi).

uniquely qualified to chair the Hui Whakamaarama. As the Head of Medicine at Wellington Hospital, the author of two influential reports on Maori health, and the Director of Te Manawa Hauora, one of two Maori health research centres established in 1992 by the Health Research Council and Te Puni Kokiri, he had the academic, scientific, and personal attributes required. Over 100 health workers from around New Zealand attended the hui, including leading medical experts in epidemiology, gastroenterology, and public health.<sup>75</sup>

In the report of the proceedings, Pomare located the debate over screening amongst Maori within the framework of the major health care reforms instigated by the National Government after coming to power in late 1990. The report described the health reforms, which were radical and wide-ranging, as offering both ‘threats and opportunities’ for Maori.<sup>76</sup> In mid-1991, Health Minister Simon Upton had dismissed the area health boards, replacing them with commissioners and separating the funding, purchasing and provision of health care. A newly created Public Health Commission was given responsibility for purchasing health protection, promotion and disease prevention services on a population-wide basis.<sup>77</sup> While this competitive ‘market driven’ model of healthcare had drawbacks for Maori, it also offered new opportunities to participate in the delivery of health care, and to provide primary health programmes tailored to the specific cultural and social needs of the Maori population.<sup>78</sup>

In the early 1990s, after almost a decade of increased involvement in the health system, Maori were poised to take greater ownership of primary health services. Pomare therefore considered Milne’s proposal for a multi-factorial screening programme in the light of the changes in the health sector and the potential for Maori to gain greater access to health

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<sup>75</sup> Te Manawa Hauora was established in 1992 by the Health Research Council of New Zealand and Te Puni Kokiri.

<sup>76</sup> *Hui Whakamaarama: Report of a Consensus Hui Concerning Screening Amongst Maori*, p.7.

<sup>77</sup> M. Laugesen, G. Salmond, ‘New Zealand health care: a background’, *Health Policy*, 29, July 1994, pp.11-23.

<sup>78</sup> For further discussion of the impact of the health reforms on Maori, see P. Laing, E W. Pomare, ‘Maori health and the health care reforms’, *Health Policy*, 29, 1994, pp.143-56; M. Durie, *Whaiora: Maori Health Development*, pp.173-7; see also J. Kelsey, *The New Zealand Experiment: A World Model for Structural Adjustment?*, p.217, and R. Gauld, *Revolving Doors: New Zealand’s Health Reforms – the Continuing Saga*, pp.72-6.

care. In outlining the specific health problems affecting Maori, he stated that ‘One could argue that we should direct our energies in to key issues such as smoking, nutrition and alcohol, as opposed to introducing screening programmes’, and asked ‘what priority are we going to place on screening in the context that there are very many problems affecting Maori people which impinge on health’.<sup>79</sup> Further, the report of the Hui Whakamaarama noted that although the idea of opportunistic screening to detect early signs of disease was initially attractive, ‘there were issues ... [as to] ... whether a programme such as this offered the best investment ... for Maori health development’.<sup>80</sup>

The report recommended that health workers and communities make use of Jungner and Wilson’s 1968 screening criteria to ensure that screening proposals were critically evaluated before programmes were introduced. In a background paper that drew heavily from a 1990 Nuffield Trust monograph written by prominent UK epidemiologists Dr Walter Holland and Dr Susie Stewart, it cautioned that ‘screening should be a hard-headed professional exercise rather than a form of evangelism’ and that screening programmes should be integrated into a broader plan for health improvement.<sup>81</sup>

Pressure groups, together with the media, may excite a public demand for screening leading to a kind of crusade against a particular disease ... as a result governments may be persuaded to provide a screening service before a comprehensive and scientifically respectable assessment of its benefit is available.<sup>82</sup>

Senior members of the medical profession attending the hui endorsed these views. Dr Cliff Tasman-Jones, in particular, was critical of the proposal to screen more widely for hepatitis B carriers before the costs and benefits of a screening programme had been fully assessed. Tasman-Jones, a gastroenterologist and senior lecturer at the Auckland School of Medicine, had chaired the MRC Working Group on Viral Hepatitis in the mid-1980s.

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<sup>79</sup> *Hui Whakamaarama: Report of a Consensus Hui Concerning Screening Amongst Maori*, pp.25-6.

<sup>80</sup> *ibid.*, p.6.

<sup>81</sup> *ibid.*, W. Holland and S. Stewart, *Screening in Health Care – Benefit or Bane?*, London, 1990, cited in Appendix 1: Policy, Planning, Provision, and Monitoring, p.2.

<sup>82</sup> *ibid.*, p.1.

Like Pomare, he was a supporter and trustee of the newly formed Hepatitis Foundation, of which Milne was the director.<sup>83</sup>

In Tasman-Jones' opinion, the only benefits of population-based hepatitis B screening were the opportunities it offered for carriers to undertake lifestyle changes and to provide immunisation for their susceptible contacts. In his professional role, he had treated hepatitis B carriers with interferon, but had found that it was only suitable for a 'select few' patients for whom treatment was not 100 per cent effective. Furthermore, Tasman-Jones believed that hepatitis B screening had the potential to do harm by 'creating fear and uncertainty in carriers'. He argued that even though hepatitis B was of particular importance to Maori health, it was essential that effective treatment and follow up services were available before a population-based screening programme was introduced.<sup>84</sup>

Milne, on the other hand, argued forcefully in favour of the introduction of a nationwide hepatitis B screening programme. He claimed that it was unnecessary to have services or treatment available for carriers identified in the screening process: 'Everybody says you've got to make sure downstream services are in place and I say "baloney" ... What you do is you assess the problem and see if you can fix it, and if you think you can, you go ahead and try and do it'. In Milne's view, official reluctance to undertake a programme to identify and follow up hepatitis B carriers was not the result of careful assessment of the criteria for screening, but an example of deliberate neglect by predominantly Pakeha decision-makers. He asserted that 'if the problem of hepatitis B had been as bad for Europeans as it was for Maori, we would have seen [government] action a long time ago'.<sup>85</sup>

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<sup>83</sup> In November 1992, the Hepatitis Research Unit and Hepatitis Control Trust were incorporated into the Hepatitis Foundation, which moved to new premises off the Whakatane Hospital site. Vivien Edwards attributed the move to 'continuing controversy' surrounding the HRU's school immunisation programme, which was 'threatening Whakatane Hospital's funding'. *Battling the Big B: Hepatitis B in New Zealand*, p.78.

<sup>84</sup> *Hui Whakamaarama: Report of a Consensus Hui Concerning Screening Amongst Maori*, p.35.

<sup>85</sup> *ibid.*, p.36.

Milne took the opportunity provided by the hui to promote the work of the Hepatitis Foundation: ‘We are now running ... the only privately funded surveillance programme in the world for hepatitis B carriers, most of whom are Maori, [and] most of whom are children’. He informed the participants that ‘The model we are working with was inspired by a group in Alaska. We wanted to do the job right, we checked out the message and we’ve looking after the carriers.’ When it came to gains from screening, however, Milne offered only two: ‘You can give lifestyle advice on sex, alcohol etc’, and, ‘If we can come up with an affordable treatment, the carriers on record will be the first to benefit.’<sup>86</sup>

The Hui Whakamaraama exposed deeply divided opinions on the value of hepatitis B screening and opposing views on the need for a critical approach to the planning and implementation of screening programmes. What is more, Milne’s analysis of events construed criticism of his plans to develop a screening programme as evidence of a political framework that promoted the interests of Pakeha to the detriment of Maori. Any opposing views could be interpreted as not only anti-hepatitis B screening, but as anti-Maori.

### **Irreconcilable views**

The views expressed by Alexander Milne and Cliff Tasman-Jones on hepatitis B screening at the Hui Whakamaarama, which represented the extreme opposites of the screening debate, were an early indication of the difficulties that lay ahead in developing unanimous recommendations on hepatitis B screening. Even though they had worked together successfully in developing guidelines for the management of individual hepatitis B carriers, they held sharply divergent views on the benefits of population-based hepatitis B screening.<sup>87</sup>

In 1993, a combination of continued ministerial lobbying by Milne, reports of unsatisfactory follow up of hepatitis B carriers in public hospitals, and the unresolved

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<sup>86</sup> *ibid.*, pp.36-7.

<sup>87</sup> Tasman-Jones was a member of the first Working Party on the Control of Hepatitis B, organised under the auspices of the HRU in 1991. C.D. Moyes, *Management of Hepatitis B Carriers: A Guide for Health Professionals*, p.1.

issue of multifactorial screening for Maori, contributed to the decision to form an advisory group on hepatitis B screening.<sup>88</sup> In early 1994, Christopher Lovelace, the Director-General of Health, appointed a Health Department Working Party chaired by Tasman-Jones to make recommendations on hepatitis B screening policy.<sup>89</sup>

The terms of reference of the working party defined four areas of investigation and debate: the value of population-wide screening to identify hepatitis B carriers, the effectiveness of screening identified carriers for liver disease, the usefulness of multifactorial screening, and the ways in which services for hepatitis B carriers could be most effectively delivered, taking into account the special needs of Maori.<sup>90</sup> In recognition of the high prevalence of hepatitis B carriage among the Maori and Pacific populations and the statutory obligation of the government and the health services to consult with Maori on matters pertaining to their health, Maori and Pacific interests were well represented on the working party.<sup>91</sup>

From the start, however, consensus appeared unlikely. Tensions soon became evident between Milne and the other members of the working party.<sup>92</sup> While the majority of the members advocated a critical evaluation of the costs and benefits of screening, pointing to the potential for negative psychological effects from identification as a hepatitis B

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<sup>88</sup> See for example, D. McLeod, J. O'Hallohan, G. Durham, 'The follow-up of hepatitis B positive patients at Hutt Hospital', *CDNZ*, 93, 4, April 1993, pp.49-54; Milne to Patel, 'NZCDC Report on Hepatitis B', 16 November 1993, AGBX 16127 W5189 53 MA 4/4/1 1995, ANZW.

<sup>89</sup> The core group included the chair, Professor Cliff Tasman-Jones, Peter Hunter, senior policy analyst, Ministry of Health, Alexander Milne, Hepatitis Advisor, Whakatane, Dr Charlotte Paul, epidemiologist, Dunedin, Merepeka Sims, Maori Health Advisor, Lake Rotoiti, and Dr Mark Thomas, infectious diseases specialist, Auckland. Professor Eru Pomare and Dr Colin Tukuitonga were appointed in the role of correspondent members to review and comment on the findings of the group.

<sup>90</sup> Ministry of Health, *Screening and Hepatitis B Infection in New Zealand: Report to the Director-General of Health of the Working Party on Hepatitis B*, Wellington, 1994, pp.4-5.

<sup>91</sup> The Health and Disability Act 1993 provided a statutory requirement for the purchasers of health services (Regional Health Authorities) to consult with the community. Section 34 of the Act specified that the special needs of Maori be taken into account. In July 1993, Simon Upton, the Minister of Health, published objectives for all Regional Health Authorities in which the overall Government objective for Maori health was restated: 'Seek to improve the health status of Maori, so that in the future Maori will have the opportunity to enjoy the same level of health as non-Maori'. M. Durie, *Whaiora: Maori Health Development*, p.176.

<sup>92</sup> Cliff Tasman-Jones later recalled that 'when I was asked to chair the working party, it seemed easy at the start. But to get agreement was just so difficult'. C. Tasman-Jones, interviewed by D. M. Jowitt, 26 October 2006.

carrier, including stigmatisation and anxiety, Milne strongly supported screening for hepatitis B carriers and regular surveillance of identified carriers for signs of liver disease. He pointed to the apparent inconsistency of screening blood donors for hepatitis B to benefit others, when adults in high risk groups and their close contacts were missing out on the potential benefits offered by a coordinated screening programme.<sup>93</sup>

Despite Milne's protestations, the majority of the working party was in agreement that the advantages to carriers of introducing a nationwide screening programme, including counselling, education and immunisation of contacts, were insufficient to offset the potential psycho-social disadvantages of being identified as a hepatitis B carrier.<sup>94</sup> Further, they agreed that the only available anti-viral drug, interferon, would have limited usefulness for New Zealand carriers infected as infants or young children.<sup>95</sup> To gather more information on interferon treatment and screening for the early detection of liver cancer, they recommended that randomised controlled trials should be undertaken among local carriers to assess the 'benefits, costs and acceptability' of these interventions.<sup>96</sup> Milne objected strongly to this recommendation, describing the proposed research as 'unethical' and 'unconscionable'.<sup>97</sup> From his perspective, no further studies were needed to confirm the benefits of a hepatitis B screening and surveillance programme coordinated by the Hepatitis Foundation.

The key recommendation of the 1994 report was that 'increased culturally appropriate community education concerning hepatitis B prevention and the consequences of infection [should be made available] ... particularly for groups at increased risk such as Maori and Pacific Islands people'.<sup>98</sup> While the other members of the working party regarded the health funding arrangements introduced by the 1991 health reforms as an opportunity for Maori to provide 'culturally appropriate' education and counselling, and

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<sup>93</sup> Ministry of Health, *Screening and Hepatitis B Infection in New Zealand: Report to the Director-General of Health of the Working Party on Hepatitis B*, pp.43-57.

<sup>94</sup> *ibid.*, pp.24-5. These disadvantages included disease labelling and discrimination, as well as the potential for increased anxiety and morbidity.

<sup>95</sup> *ibid.*, pp.26-32.

<sup>96</sup> *ibid.*, pp.50-1.

<sup>97</sup> *ibid.*, Appendix 6: Dissenting Opinion by Mr A. Milne, p.1.

<sup>98</sup> *ibid.*, p.44.



to ‘address their aspirations ... to manage health strategies for their people’ by providing hepatitis B programmes, Milne disagreed.<sup>99</sup> In his view, the Hepatitis Foundation was the only organisation equipped to introduce initiatives for hepatitis B control in high risk communities, and the only one to have demonstrated consistent concern for the welfare of hepatitis B carriers. He attached a dissenting opinion to the final report of the working party in which he argued that the only way to ensure ‘proper’ care for carriers was for the Hepatitis Foundation to coordinate a screening and surveillance programme.<sup>100</sup>

Despite this apparent setback, Milne persisted with his screening campaign. After attempting to gain funding for hepatitis B screening from the Midland Regional Health Authority and the Ministry of Health, he lobbied members of the Parliamentary Maori Affairs Committee for a formal hearing into the carrier issue. Milne’s pro-screening stance clearly impressed the committee, which was chaired by Koro Wetere, Minister of Maori Affairs under the former Labour Government. In July 1995, representatives from the Ministry of Health, Te Puni Kōkiri, and the Hepatitis Foundation were invited to brief the Maori Affairs Select Committee on hepatitis B screening programmes for Maori.<sup>101</sup>

Milne presented a strongly worded submission in favour of a screening programme coordinated by the Hepatitis Foundation. He was highly critical of the Ministry of Health and the recommendations of the 1994 report, which he described as ‘dangerous nonsense’, ‘impractical and unworkable’ for Maori, and ‘so unethical that if implemented they would parallel the “Unfortunate Experiment” at National Women’s Hospital’.<sup>102</sup> He portrayed the Ministry of Health and its advisors as ‘against screening, and against

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<sup>99</sup> *ibid.*, p.53.

<sup>100</sup> B. J. McMahon, T. London, ‘Workshop on screening for hepatocellular carcinoma’, *Journal of the National Cancer Institute*, 83, 3 July 1991, pp.918-9.

<sup>101</sup> Membership of the Maori Affairs Committee in July 1995 was as follows: Koro Wetere (Chairman), Pauline Gardiner, Tau Henare, Michael Laws, Graeme Lee, Sandra Lee, Roger McLay, Tony Ryall and Whetu Tirakatene-Sullivan.

<sup>102</sup> Milne was referring to a controversial inquiry into the medical management of women with pre-cancerous cervical lesions at National Women’s Hospital in Auckland, which followed a sensational 1987 *Metro* article entitled ‘An Unfortunate Experiment at National Women’s Hospital’, P. Bunkle, S. Coney, *Metro*, June 1987, pp.46-65; ‘The Report of the Cervical Cancer Inquiry’, 1988; Maori Affairs Committee, *Report of the Maori Affairs Committee: Hepatitis B Screening Programme for Maori*, Wellington, 1995, Appendix B: Papers of the Hepatitis Foundation, p.10; p.15.

treatment’ of carriers, asserting that ‘in the US this sort of neglect ... would be the subject of a class action suit’.<sup>103</sup>

Ministry officials presented a different slant on the screening issue.<sup>104</sup> They argued that during 1993 and 1994, the Public Health Commission had developed a comprehensive consultation process with Iwi on public health issues. Twenty four hui were held to provide clear direction from Maori on a strategic plan for Maori health, *He Matariki*.<sup>105</sup> Taking into account the other serious threats to Maori health such as heart disease, the only recommendation related to hepatitis B to emerge from the consultative process was to strengthen hepatitis B immunisation in the context of improving protection against vaccine-preventable diseases among Maori children.<sup>106</sup> Furthermore, the Ministry stated that in 1994, Te Ara Ahu Whakamua (the Maori Health Decade Hui), had clearly indicated a desire by Maori to take more responsibility for their own health, and that these sentiments had been repeated at national hui held in Palmerston North in 1994, and in Ngaruawahia in early 1995.<sup>107</sup> From this perspective, Ministry officials and representatives of Te Puni Kokiri claimed that the 1994 Working Party report reflected both Maori aspirations and Ministry policy.

In response to Milne’s accusations that the Ministry supported the guidelines for the management of hepatitis B carriers developed by the Hepatitis Foundation in 1991, health officials emphasised that there was a significant difference between a nationwide programme of hepatitis B screening and carrier surveillance, and the management of

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<sup>103</sup> *ibid.*, pp.38-40.

<sup>104</sup> Ministry of Health, *Briefing to the Maori Affairs Committee: Hepatitis B Screening Programme for Maori*, Wellington, 1995.

<sup>105</sup> PHC, *He Matariki: A Strategic Plan for Maori Health. He Kaupapa Whaingā Roa Mo Te Hauora Tūmatanui Maori. The Public Health Commission’s Advice to the Minister of Health 1994-95*, Wellington, 1995.

<sup>106</sup> ‘Circulatory’ diseases were estimated to cause 520 deaths annually among Maori, compared with approximately 100 from the longterm complications of hepatitis B. Ministry of Health, *Briefing to the Maori Affairs Committee: Hepatitis B Screening Programme for Maori*, Appendix B: Papers of the Hepatitis Foundation, p.24; Appendix C: Papers of the Ministry of Health, p.45.

<sup>107</sup> These were the Hui Whakapumau, held at Massey University in August 1994, and the Wananga Purongo Kororero held in Ngaruawahia in February 1995. *ibid.*, pp.51-2.

individual hepatitis B carriers under the guidance of clinical protocols.<sup>108</sup> They argued that the best way to provide education and support for Maori carriers was through health services managed by Maori providers, and that the Ministry would not support stand-alone population-based screening programmes until there was clear evidence that such programmes would produce benefits for carriers.<sup>109</sup>

For his part, Milne was adamant that his standpoint on hepatitis B screening had strong support among Maori. He insisted that Eru Pomare and Merepeka Sims, the two Maori members of the 1994 working party, had agreed with the dissenting views he had appended to its report. Ministry officials disputed Milne's version of events, claiming that Pomare had 'suggested targeting a geographical area of increased risk with whanau-based comprehensive lifestyle education along with opportunity for vaccination and detection and management of carriers'. Moreover, they contended that Pomare had envisaged the Hepatitis Foundation as a potential adviser to Maori health providers, rather than as the sole provider of services, because he believed that 'High risk groups should manage these programmes for their own people to utilise community infrastructures for support and to empower community health initiatives.'<sup>110</sup> While it appeared that Sims had subsequently given her support to Milne, Pomare's untimely death in January 1995 left uncertainty over his final position on the screening issue.

In the event, the Maori Affairs Committee was won over by Milne's passionate approach to carrier management. In its report, tabled in Parliament in October 1995, the committee concluded that the Hepatitis Foundation was the only agency ready and able to offer practical assistance to Maori carriers.<sup>111</sup> On the basis of Milne's claim that medical practitioners had changed their views on screening to come in line with 'the concerns expressed by the Foundation's representative on the [1994] working group', it recommended that the Ministry of Health should review the 1994 Working Party report.

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<sup>108</sup> See for example, the guidelines prepared in 1991 for the clinical management of individual carriers: C. D. Moyes, *Management of Hepatitis B Carriers: A Guide for Health Professionals*.

<sup>109</sup> *Report of the Maori Affairs Committee: Hepatitis B Screening Programme for Maori*, Appendix C: Papers of the Ministry of Health, pp.52-3.

<sup>110</sup> *ibid.*, p.51.

<sup>111</sup> *ibid.*, pp.52-3.

The committee also recommended that a screening programme be established as soon as practicably possible, and that the Ministry of Health and Te Puni Kokiri give financial support to the Hepatitis Foundation for carrier screening and follow up.<sup>112</sup>

Hence, the invitation to brief the Maori Affairs Committee in May 1995 provided Milne with a renewed opportunity to challenge the recommendations of the 1994 working party, and to question the motives of the Ministry of Health and Te Puni Kokiri with regard to hepatitis B carriers. His highly emotive presentation on the benefits of hepatitis B screening, particularly for Maori carriers, proved more persuasive to the committee than the cautious analysis provided by the Ministry of Health.<sup>113</sup>

### **‘A political hot potato’**

The 1995 report of the Maori Affairs Committee was well-received in some quarters, but it found little favour with Jennifer (Jenny) Shipley, the Minister of Health. While she had a statutory obligation to respond to the report, Shipley had reservations about Milne’s submission and some of the committee’s key recommendations.

In February 1996, Shipley tabled her response to the recommendations of the Maori Affairs Committee report in Parliament. She observed that there were inconsistencies in Milne’s submission to the committee, including his unsubstantiated claim that ‘practitioners had changed their approach to hepatitis B in line with [his] concerns’.<sup>114</sup> She also commented that Milne was the only member of the 1994 working party to have had the opportunity to appear before the Maori Affairs Committee, which unfairly prejudiced its findings.<sup>115</sup> Nevertheless, she had concurred with the committee’s call for an independent review of the 1994 report. Not only was she faced with an increasingly contentious public health issue but she was aware that an impartial oversight was

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<sup>112</sup> *ibid.*, p.6.

<sup>113</sup> *ibid.*, pp.10-23.

<sup>114</sup> *Government Response to the Report of the Maori Affairs Committee on Hepatitis B Screening Programme*, Wellington, February 1996, p.6.

<sup>115</sup> *ibid.*

required to defuse the tensions created by the acrimony of the accusations levelled by Milne at members of the 1994 working party and the Ministry of Health.<sup>116</sup>

Unlike Shipley, the Maori community had welcomed the recommendations of the Maori Affairs Committee. Milne's claim that the Pakeha-dominated health system had deliberately ignored 'the plight of hepatitis B carriers in New Zealand' rang true for many Maori, who were aware of the significant disparities between the health of Maori and European New Zealanders.<sup>117</sup> They took a bleak view of government reluctance to provide a national hepatitis B screening programme, which, from their perspective, had parallels with the sluggish response to the repeated calls for a childhood hepatitis B immunisation programme in the 1980s.

The authors of the Maori Law Review, for example, described the contents of the report as 'a sorry and cautionary tale of inaction' on the part of the Ministry of Health. They concluded that the statutory requirement for Regional Health Authorities (RHAs) to consult with the community and take the special needs of Maori into account, 'appears to have allowed the RHAs, the Ministry of Health and Te Puni Kokiri to disregard mounting concern expressed by the Hepatitis Foundation that a screening programme was urgently required and insist that nothing more than community education programmes about the disease were needed'.<sup>118</sup> In his *Metro* column 'Te Karanga', Dr Ranginui Walker, a leading Maori academic, called the Ministry of Health's hepatitis B policy a 'penny-pinching save-and-hope strategy'. He argued that the Ministry was maintaining a position of callous disregard for carriers in the expectation that 'with the immunisation of children, the disease will fade away as the present generation of carriers dies off'.<sup>119</sup>

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<sup>116</sup> *ibid.*, p.3; see also, Thomas to Wetere (draft), 9 November 1995; Paul to Thomas, 13 November 1995, in private possession.

<sup>117</sup> *Briefing to the Maori Affairs Committee: Hepatitis B Screening Programme for Maori*, Appendix B: Papers of the Hepatitis Foundation, p.10; For comparative health statistics in the early 1990s, see for example, the Public Health Commission publication, *Our Health, Our Future, Hauora Pakari, Koiora Roa: The State of the Public Health in New Zealand*, Wellington, 1993.

<sup>118</sup> 'The Maori Law Review', October 1995, online, available at: <http://bennion.co.nz/mlr/1995/oct.html> (1 February 2009).

<sup>119</sup> R. Walker, 'Te Karanga: WHOse Problem?', *Metro*, 176, May 1996, pp. 126-7.

In late 1995, Shipley had commissioned Professors Leon Gordis and Kenrad Nelson, epidemiologists at the Johns Hopkins School of Medicine, Philadelphia, to review the 1994 working party report.<sup>120</sup> Gordis and Nelson concluded that given the uncertainty about the costs and benefits of hepatitis B screening programmes, it would be useful to undertake ‘a pilot programme in a one geographical area for the primary purpose of obtaining more rigorous data’. Like the majority of the 1994 working party, they regarded available treatment for the carrier state as suitable for ‘only an occasional patient’, and that this was insufficient justification for the immediate introduction of a nationwide hepatitis B screening programme.<sup>121</sup>

On the basis of Gordis and Nelson’s recommendations, and ongoing lobbying by the Maori Affairs Committee, Shipley reconvened the Ministry of Health hepatitis B working party in March 1996.<sup>122</sup> Cliff Tasman-Jones, who was asked to return to the role of chairman of the working party in view of his expertise and ‘the complex issues involved’, initially declined on the grounds that he had ‘done his bit’ and might be seen by some as an ‘adversary’. However, when Shipley asked him to reconsider her request, he agreed.<sup>123</sup> Chris Moyes was appointed in recognition of his experience in carrier management, and Milne was among those appointed from the original members of the group, giving the Hepatitis Foundation two representatives on the thirteen member committee.<sup>124</sup>

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<sup>120</sup> L. Gordis and K. Nelson, *Evaluation of Screening and Hepatitis B Infection in New Zealand: Report of June 1994 to the Director-General of Health of the Working Party on Hepatitis B*, Baltimore, 1996.

<sup>121</sup> *ibid.*

<sup>122</sup> Koro Wetere, Chairman of the Maori Affairs Select Committee, coordinated a meeting with Shipley to ‘assess the need for a further inquiry’ into hepatitis B screening for Maori on 20 March 1996. Wetere to Thomas, 8 March 1996, in private possession.

<sup>123</sup> C. Tasman-Jones interviewed by Deborah Jowitt, 26 October 2006.

<sup>124</sup> The 13 member working party included Professor Clifford Tasman-Jones, Chair, Dr Bruce Chapman, gastroenterologist, Dr Gillian Durham, Director of Public Health, Lorna Dyal, Maori Health Advisor, Dr Martin Entwistle, Regional Health Authority representative, Dr Terri Green, Health Services Research and Evaluation, Alexander Milne and Dr Chris Moyes, Hepatitis Foundation, Tim Rochford, Advisor Maori Public Health, Merepeka Sims, Maori Health Advisor, Dr Kim Leong Szeto, economist, Ministry of Health, Dr Phil Weinstein, epidemiologist, Public Health Intelligence, John Whaanga, Maori Public Health Policy, Ministry of Health, with Associate Professor Charlotte Paul, epidemiologist, and Dr Colin Tukuitonga, public health physician and Pacific advisor as respondent members.

Milne was openly critical of the plan to reconvene the working party. In the press, he called the proposal a government ‘stalling’ tactic.<sup>125</sup> There was no doubt as to his objectives; Vivien Edwards’ history of the Hepatitis Foundation frankly stated that ‘Milne set about trying to have the new working party disbanded’.<sup>126</sup> When the working party produced a report in September 1996, he called the recommendation to undertake a pilot programme before a definitive decision was made on screening policy ‘misguided and dangerous’, claiming that ‘all the information to justify screening has been available since 1991. The delay ... since that time has been unconscionable and must not be extended by an unnecessary and wasteful pilot programme’.<sup>127</sup> Once again, Milne appended his formal reservations to the working party’s report.<sup>128</sup>

In a strategy reminiscent of the immunisation campaign, Milne took his message to the media. The *Dominion*, which had been a staunch supporter of state-funded hepatitis B immunisation, provided close coverage of his views. In September 1996, when Shipley endorsed the recommendations of the working party for a two year pilot programme to be undertaken in South Auckland and Northland, followed by a national screening programme if the pilot was both ‘feasible and cost-effective’, the *Dominion* published Milne’s response, an open letter to Shipley in which he claimed he had been marginalised by the Ministry of Health and made to look like a ‘lone dissenter’.<sup>129</sup> Further, on the high-rating television current affairs programme, *Holmes*, Milne challenged Gillian Durham, the Director of Public Health and a fellow member of the working party, to justify the Ministry of Health stance on hepatitis B screening.<sup>130</sup>

In early October 1996, the country went to the polls. It was the first election under the new mixed member proportional (MMP) voting system, and neither of the major parties took enough seats to govern alone. To form a majority government, Jim Bolger, the

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<sup>125</sup> ‘Costs stall screening trial, says foundation’, *Dominion*, 24 February 1996.

<sup>126</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.118.

<sup>127</sup> ‘Report recognises hepatitis B fears’, *Dominion*, 13 September 1996.

<sup>128</sup> ‘Third Working Party (1996) on Hepatitis B: Reservations and Comments by Mr Alexander (Sandor) Milne’, *Report to the Director-General of Health of the Working Party on Hepatitis B: The Feasibility of Screening for and Surveillance of Hepatitis B in a Single Geographic Area*, Wellington, 1996.

<sup>129</sup> ‘Shipley criticised over hepatitis B problems’, *Dominion*, 28 September 1996.

<sup>130</sup> Paul Holmes interview with Gillian Durham, *Holmes*, 26 September 1996, P174779, TVNZ Archives.

National Prime Minister, entered into protracted negotiations with Winston Peters, the leader of the New Zealand First Party, which had won seventeen seats, including all five Maori electorates.<sup>131</sup> The National New Zealand First coalition, announced two months after the election, introduced a powerful new Maori lobby into Parliament.<sup>132</sup>

The election results had a profound effect on the screening issue. In late October 1996, the *New Zealand Doctor* reported that the screening debate had become increasingly contentious, and that Milne's supporters took a strong view of the Ministry's perceived reluctance to act on behalf of its Maori constituents. The medical magazine predicted that 'the issue has the potential to become a political hot potato with Tuariki John Delamere, New Zealand First MP for Te Tai Rawhiti, pledging to support the position of the Hepatitis Foundation and to make hepatitis B screening a priority in Parliament'. According to the article, Delamere attributed his decision to the wishes of the late 'respected health campaigner Eru Pomare'.<sup>133</sup>

Through his repeated forays into the media, therefore, Milne succeeded in raising the public profile of the Hepatitis Foundation and its pro-screening position. By the end of 1996, in spite of the ministerial working party recommendation for a preliminary pilot to evaluate the costs and benefits of screening, he had produced a groundswell of political support for the urgent introduction of a national hepatitis B screening programme.

### **A 'national' screening programme**

In December 1996, Bolger announced the line up of the Coalition Cabinet. New Zealand First MPs figured prominently, creating potential for a change in hepatitis B policy. Winston Peters held the position of Deputy Prime Minister and Treasurer, a new role senior to the Minister of Finance, while Tuariki John Delamere was appointed as Associate Minister of Health and Finance.

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<sup>131</sup> In the 1996 general election, the National Party took 44 seats while the Labour party took 37. 'New Zealand Election Results', online, nd, available at: <http://www.electionresults.govt.nz/> (2 February 2009). Before the 1996 election, the number of Maori seats was increased from four to five. 'Maori and the Vote', online, nd, available at: <http://www.elections.org.nz/democracy/history/maori-vote.html> (2 February 2009).

<sup>132</sup> 'History of the National Party', online, nd, available at: <http://national.org.nz/About/history.aspx> (2 February 2009).

<sup>133</sup> M. Aggett, 'Hepatitis B pros and cons debated', *New Zealand Doctor*, 30 October 1996, p.56.



In early 1997, tensions between the members of the governing coalition delayed plans to introduce a pilot screening programme, however, in the June 1997 budget \$8 million was allocated for a pilot hepatitis B screening programme for South Auckland and Northland.<sup>134</sup> In the meantime, Milne continued to seek support for a fully funded national screening programme directed by the Hepatitis Foundation. Confident that Maori were sympathetic to his campaign, he lobbied MPs on the Maori Affairs Select Committee, urging them to challenge the government's cautious approach to initiating a screening programme. At a hearing held by the committee in September 1997, two weeks before community consultation on the pilot screening programme was due to start, the Health Minister, William (Bill) English, faced considerable pressure from both government and opposition Maori MPs, who accused the Ministry of Health and the government of stalling on the screening programme while Maoris died 'in huge numbers'.<sup>135</sup>

Milne's political activity achieved his desired result. In early July 1998, just as contracts were about to be finalised with service providers, the pilot project was abandoned.<sup>136</sup> Instead, Peters announced that Cabinet had set aside \$22.5 million to implement a national screening programme over the next three years. The Health Funding Authority (HFA), which had been formed by the amalgamation of the four RHAs in early 1998, was given responsibility for purchasing services for the new project, planned to start in early 1999.<sup>137</sup> The apparently arbitrary policy turnaround was due largely to the successful lobbying of Peters and his New Zealand First MPs, many of whom were Maori, and who had significant political influence as a result of the governing coalition arrangement. Such a striking reversal in policy suggested that the final intent and size of

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<sup>134</sup> '\$8 million set for pilot', *New Zealand Doctor*, 9 July 1997.

<sup>135</sup> 'Government handling of hepatitis "ruthless"', *Dominion*, 17 September 1997.

<sup>136</sup> Considerable time and resources had already gone into preparing for the pilot programme and the tender process. See for example, T. Blakely, P. Crampton, P. Weinstein, and A. Woodward, *Hepatitis B Screening and Follow-up Programme in Defined Geographical Area/s: Epidemiological Framework for the Evaluation, Report for North Health October 1997*, Department of Public Health, Wellington School of Medicine, 1997; 'National hepatitis B screening programme scaled down', *New Zealand Doctor*, 11 November 1998, which claimed that \$300,000 had been spent on the pilot project.

<sup>137</sup> 'National screen for hepatitis B', *New Zealand Doctor*, 8 July 1998.

the screening programme was shaped more by political considerations, than by scientific evidence or research.<sup>138</sup>

The dramatic changes in policy caused disquiet among public health professionals. In September 1998, Dr Tony Blakely and Dr Craig Thornley, public health registrars at the Wellington School of Medicine, presented a submission to the Minister of Health, Treasurer and Minister of Finance, requesting a reinstatement of the pilot programme.<sup>139</sup> ‘Information obtained under the Official Information Act’, they argued, ‘showed that the Cabinet decision to [cancel the pilot] was contrary to advice from the HFA ... the Treasury ... and Te Puni Kokiri’. Further, they claimed that an ethnically ‘targeted population-based national programme *delivered in the manner envisaged by the Hepatitis Foundation* [their emphasis]’ was likely to be ‘inadequate in coverage ... ineffective ... and unethical’.<sup>140</sup> In the foreword, Cliff Tasman-Jones made an impassioned plea for Cabinet to review its decision and ‘avert a tragedy’. By cancelling the pilot programme, he contended that the Government had lost the opportunity to develop ‘what could have been a standard setter for other [screening] programmes and [what] would have shown New Zealand to be a world leader in this area of public health’.<sup>141</sup>

In 1999, Blakely and Thornley published a retrospective review of policy development for hepatitis B screening.<sup>142</sup> They described the policy making process as ‘not chaotic, but certainly erratic’.<sup>143</sup> Drawing attention to the lack of international evidence on screening and treatment for hepatitis B carriers, they called upon decision makers to ensure an evaluation was undertaken early in the programme and depending on the

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<sup>138</sup> In their 2005 guide to screening, UK epidemiologists Walter Holland and Susie Stewart noted that while the ‘great’ enthusiasm for screening among health professionals had waned since the early 1990s, politicians had become far more convinced of the need for screening services, ‘perhaps reflecting popular opinion’. *Screening in Disease Prevention: What works?*, p.14.

<sup>139</sup> T. Blakely, C. N. Thornley, *Screening and Follow-up of Hepatitis B Carriers in New Zealand: Submission to the Minister of Health and Treasurer and Minister of Finance, 28 September 1998*, private papers, T. Blakely.

<sup>140</sup> *ibid.*, p.2.

<sup>141</sup> *ibid.*, p.4.

<sup>142</sup> T. Blakely, C. N. Thornley, ‘Screening for hepatitis B carriers: evidence, and policy development in New Zealand’, *NZMJ*, 112, 12 November 1999, pp.431-3.

<sup>143</sup> *ibid.*, p.432.

results, to have ‘the courage to stop any screening programme if initial evidence suggests that it is either unfeasible, or unlikely to be cost-effective’.<sup>144</sup>

In its screening proposal, the Hepatitis Foundation had claimed that a national programme could be conducted for \$22.5 million, little more than twice the cost of two localised pilot programmes. The HFA found fault with these figures, however, and in late 1998, it announced a hybrid proposal based on a budget of \$16.25 million, with a request for tenders from potential providers to deliver a three year hepatitis B screening programme targeting high risk communities in the North Island.<sup>145</sup>

In May 1999, contracts for screening and follow up of carriers were awarded to the Hepatitis Foundation and the Northern Region Hepatitis Consortium, which included the Auckland District Health Board, Ngati Whatua, and Maori and Pacific primary care organisations. The Consortium was responsible for screening and follow up of Maori, Pacific and Asian people aged 15 years and over in the Auckland and Northland regions, while the Hepatitis Foundation was responsible for screening and follow up of these ethnic groups in all other regions in the North Island.<sup>146</sup> As Auckland hepatologist Dr Edward Gane explained, ‘The 15 to 40 age group was a particular focus of the programme as this group was to be seen to have most to gain from both immunisation if non-immune, and surveillance if [found to be a hepatitis B carrier].’<sup>147</sup>

The two organisations used different methods to reach high risk groups. The Foundation, which began screening in July 1999, employed teams of phlebotomists that used caravans as mobile clinics to reach communities at sporting venues, shopping centres and public events, whereas the Consortium strategy worked through family doctors and Maori and

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<sup>144</sup> *ibid.*, p.433.

<sup>145</sup> *ibid.*, p.432.

<sup>146</sup> ‘Whakatane wins hepatitis contract’, *Dominion*, 18 May 1999; T. Robinson, C. Bullen, W. Humphries, J. Hornell, C. D. Moyes, ‘The New Zealand Hepatitis B Screening Programme: screening coverage and prevalence of chronic hepatitis B infection’, *NZMJ*, 118, 11 March 2005, <http://www.nzma.org.nz.ezproxy.auckland.ac.nz/journal/118-1211/134> (20 February 2009).

<sup>147</sup> E. Gane, ‘Screening for chronic hepatitis B infection in New Zealand: unfinished business’, *NZMJ*, 118, 1211, 11 March 2005, online, available at: <http://www.nzma.org.nz.ezproxy.auckland.ac.nz/journal/118-1211/1344/content.pdf> (10 February 2009).

Pacific health providers.<sup>148</sup> Contact was made with at-risk people as opportunities arose, or through by phone call or letter, at meetings in churches and on marae.<sup>149</sup>

The Hepatitis Foundation completed screening in June 2002, while the Northern Consortium, which had initially struggled to finalise contracts with multiple providers, finished screening six months later.<sup>150</sup> Both organisations achieved similar results, with an overall coverage of 27.1 per cent of the eligible population of Maori, Pacific and Asian people.<sup>151</sup> This was much lower than the initial target of 70 per cent, even though the authors of the 2005 report on the screening programme conceded that ‘experience from cervical and breast screening in New Zealand indicate[d] that this target was always going to be difficult to attain within the time and resources available’.<sup>152</sup> While the Consortium had reasonable success engaging Pacific communities in Auckland, it had difficulties recruiting Maori men and members of the Asian community.<sup>153</sup> The Hepatitis Foundation achieved higher rates of uptake in areas such as the Bay of Plenty, where hepatitis B had a higher profile; however, in some areas attempts to encourage Maori to come forward for screening had unanticipated results.

In April 2000, the Foundation encountered criticism from members of the Pakeha community in Hastings, who were turned away from their screening caravans. In October 2000, there were further accusations of racism in Taranaki, and official complaints to Rajan Prasad, the Race Relations Conciliator.<sup>154</sup> Prasad criticised what he regarded as an unnecessary ethnic component to the screening programme. While he stated that he was

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<sup>148</sup> ‘Mobile clinics to test for hepatitis B in Waikato’, *Waikato Times*, 19 January 2000.

<sup>149</sup> T. Robinson, C. Bullen, W. Humphries, J. Hornell, C. D. Moyes, ‘The New Zealand Hepatitis B Screening Programme: screening coverage and prevalence of chronic hepatitis B infection’.

<sup>150</sup> ‘Hep B programme unravelled’, *New Zealand Doctor*, 25 October 2000.

<sup>151</sup> In total 153,605 Maori, Pacific and Asian people out of 565,000 people recorded in these groups in the Census 2001 were screened. The original target was based on the 1996 Census which recorded nearly 500,000 people in these population groups.

<sup>152</sup> As the report stated: ‘To obtain high participation levels, prolonged promotion and provision of the service is required. The national breast-screening programme ... took four years to achieve 58% coverage, with considerably lower rates among Maori and Pacific women’. T. Robinson, C. Bullen, W. Humphries, J. Hornell, C. D. Moyes, ‘The New Zealand Hepatitis B Screening Programme: screening coverage and prevalence of chronic hepatitis B infection’.

<sup>153</sup> *ibid*; Anon., ‘Maori men missed in hep B screening’, *New Zealand Doctor*, 24 October 2001.

<sup>154</sup> ‘Hepatitis screening slammed as racist’, *The Daily News*, 9 October 2000.

in favour of political action to reduce health inequalities between Maori and other New Zealanders, he believed that health and social policy initiatives introduced by the Labour Government, such as ‘Closing the Gaps’, were having the opposite effect.<sup>155</sup> In Prasad’s view, ‘affirmative-action health policies targeting Maori, such as [the] hepatitis B programme, invite[d] racial division, resentment and anger’.<sup>156</sup>

On its completion in 2002, the three-year screening programme could only claim limited success.<sup>157</sup> Described in 2005 as the ‘largest community-based hepatitis B screening programme ever conducted anywhere in the world’, it nevertheless achieved much lower levels of participation than initially planned. The reluctance of Maori and Asians to come forward for screening, the generally low awareness of hepatitis B in the community, and the experience of the breast and cervical screening programmes, all confirmed the need for a comprehensive pilot to ascertain the requirements of a ‘national’ hepatitis B screening programme.

## Conclusion

Throughout the 1990s, Milne and Moyes and the public health authorities held sharply divided views on the role of screening in public health and on the benefits that would accrue from the introduction of screening to identify and follow up hepatitis B carriers. The Health Department, and later, the Ministry of Health and the majority of its advisors steadfastly maintained that immunisation was the most effective means to prevent and control hepatitis B in New Zealand, while Milne and Moyes presented forceful arguments for the introduction of screening, particularly in high risk communities.

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<sup>155</sup> ‘Closing the Gaps’, a key feature of the June 2000 Budget, was the culmination of more than a decade of policies directed towards increasing Maori ownership of Maori health. For non-Maori New Zealanders, however, the policy raised the prospect of discrimination on ethnic grounds, no matter how pressing the social or health issues. See for example, L. Bryder, ‘Health Citizenship and “Closing the Gaps”’: Maori and Health Policy’, pp.59-60.

<sup>156</sup> ‘Editorial: Time to reassess Closing the Gaps’, NZH, 27 October 2000; ‘Prasad blames Government policy for rising racial tensions’, *The Press*, 25 November 2000; ‘Prasad blames Government for widening race rift’, *The Daily News*, 25 November 2000; ‘Government policies fuelling racial tension – Prasad’, *National News*, 25 November 2000.

<sup>157</sup> The Hepatitis Foundation is now the national provider for long-term carrier follow-up, with approximately 12,000 HBV carriers registered. ‘The New Zealand Hepatitis Foundation’, online, nd, available at: <http://www.hepfoundation.org.nz/aboutus.html> (5 February 2009).

The controversial aspects of the screening campaign reflected the divisions evident in the wider screening debate. Screening has been subject to critical review since the 1960s; however, established beliefs have been slow to change, even within the medical profession. As Angela Raffle and Sir J. A. Muir Gray observed, in 1968 ‘Wilson and Jungner were not in a position to foresee just how difficult it would be to persuade physicians, public and policy makers that screening needed to be based on evidence ... just as for any other potentially harmful medical intervention’.<sup>158</sup>

Milne, who was an unabashed screening enthusiast, promoted hepatitis B screening as a strongly positive public health measure, particularly for Maori. To bolster support for the introduction of screening, he called upon the assistance of senior figures in Maoridom who had backed his efforts to introduce a national hepatitis B immunisation programme. In the early 1990s, Maori perceived the radical reforms to the health services as an opportunity to take a more active role in programme development and service delivery.<sup>159</sup> Nonetheless, Milne made a convincing case that the Hepatitis Foundation was the most appropriate organisation to provide screening and follow up for hepatitis B carriers. By the mid-1990s, Maori were among his most vociferous supporters.

The three-year screening programme fell far short of its targeted uptake among high risk groups. The preliminary report of the project, published in 2005, could offer little more than information on the prevalence rates of hepatitis B carriage among the groups screened, and the coverage of the programme. While the report promoted the potential benefits of screening, such as carrier education, counselling and follow up, it did not define the uptake of these services. It recommended ongoing monitoring ‘to judge whether this unique programme has been effective ... and a worthwhile investment of resources’, but it did not acknowledge the opportunity costs of diverting limited funds from other important public health projects. These included childhood immunisation,

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<sup>158</sup> A. Raffle and J. A. Muir Gray, *Screening: Evidence and Practice*, pp.14-5.

<sup>159</sup> M. Durie, *Whaiora: Maori Health Development*, p.178.

despite data published in the mid-1990s that indicated only 60 per cent of Maori and Pacific children were being fully immunised against hepatitis B.<sup>160</sup>

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<sup>160</sup> T. Robinson, C. Bullen, W. Humphries, J. Hornell, C. D. Moyes, 'The New Zealand Hepatitis B Screening Programme: screening coverage and prevalence of chronic hepatitis B infection'. W. Rainger, N. Solomon, N. Jones, J. Jarman, N. Turner, D. Lennon, J. Stewart, 'Immunisation coverage and risk factors for immunisation failure in Auckland and Northland', *New Zealand Public Health Report*, 5, 7, July 1998, pp.49-51; N. Turner, M. Baker, J. Carr, O. Mansoor, 'Improving immunisation coverage: what needs to be done?', *New Zealand Public Health Report*, 7, 3/4, March/April 2000, pp.11-4.





## CHAPTER EIGHT

### HEPATITIS B IMMUNISATION POLICY

#### 1990–2005

The introduction of universal childhood hepatitis B immunisation in New Zealand in early 1990 was promoted as a major advance in hepatitis B control.<sup>1</sup> Described by the Health Minister Helen Clark as ‘the most extensive programme in the world’, all school-aged children and the close contacts of hepatitis B carriers were eligible for free hepatitis B immunisation from family doctors. In addition, to address the low uptake of hepatitis B vaccine among Maori children during the previous preschool campaign, the expanded programme provided for short-term strategies targeting children in ‘high-risk communities’.<sup>2</sup> The new policy promised a marked reduction in prevalence rates; nevertheless, the low immunisation coverage among New Zealand children suggested that additional resources would be required to achieve high uptake of the hepatitis B vaccine, especially among those children at most risk of acquiring the disease.<sup>3</sup>

This chapter will examine the factors that influenced the delivery and uptake of hepatitis B immunisation among New Zealand children between 1990 and 2005. It will begin by discussing the changes introduced in the public health sector in early 1990 and their bearing on the hepatitis B immunisation programme. It will then consider the effects of competing private ventures on the delivery of hepatitis B vaccine to ‘high risk’ children. Themes identified earlier in the thesis will re-emerge: the difficulties of reaching children at high risk of hepatitis B virus infection, the impact of health reforms on public health programmes, and the low political profile of childhood immunisation. New Zealand’s

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<sup>1</sup> Minister of Health, Media statement, ‘Hepatitis B Immunisation Programme Extended’, 27 November 1989, ABQU 632 W4452/704 131/171/4 67391.

<sup>2</sup> Minister of Health, Memorandum for Cabinet Social Equity Committee, Hepatitis B, 6 November 1989, ABQU 632 W4452/704 131/171/4 66798.

<sup>3</sup> Immunisation coverage refers to the proportion of children who have either been immunised with a specific vaccine or who have completed a vaccine series. Ministry of Health, *Immunisation Handbook 2006*, p.6.

hepatitis B immunisation programme will be compared with international efforts to control hepatitis B, and in particular, those to prevent hepatitis B transmission from carrier mothers to their babies. Finally, the chapter will conclude by considering contemporary issues in hepatitis B immunisation in New Zealand.

### **The introduction of ‘health goals and targets’**

Less than three weeks after announcing the expansion of the hepatitis B immunisation programme in late November 1989, the Health Minister Helen Clark introduced significant changes to the public health sector. Clark aimed to make more ‘effective and efficient’ use of public health funding and to reduce social and ethnic inequalities in health by concentrating available resources on clearly defined ‘health goals and targets’.<sup>4</sup> Yet despite the low levels of immunisation coverage among New Zealand children, and the significantly lower uptake of hepatitis B vaccine among Maori children during the preschool campaign, she did not include immunisation among the priority health goals.<sup>5</sup>

In mid-December 1989, Clark launched a number of public health initiatives which redefined the relationship between the Government and the public health system. These initiatives, which were the *New Zealand Health Charter*, the *New Zealand Health Goals and Targets*, and contracts between the Minister of Health and area health boards, were intended ‘to give a clearer focus and structure to the health system, particularly in ... the areas of health promotion and disease prevention’.<sup>6</sup> To complement these changes, the ‘old [Health] Department’ with its ‘many service delivery and control functions’ was replaced by a ‘lean’, ‘strategically-focused’ organisation responsible for providing policy advice, negotiating contracts between the Minister and area health boards for the delivery of public health programmes, and for monitoring progress in targeted areas of public

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<sup>4</sup> Minister of Health, *New Zealand Health Charter*, Wellington, 1989, ABQU 632 W4452/920 144/56/1 69888, ANZW.

<sup>5</sup> *ibid.*

<sup>6</sup> AJHR, December 1989, E. 10, p.3.

health.<sup>7</sup> The ‘new Department’ was launched on 1 February 1990, the same day that universal childhood hepatitis B immunisation was introduced.<sup>8</sup>

To clearly identify areas for health improvement, Clark selected ten national health goals as priorities for the public health sector until the year 2000.<sup>9</sup> The choice of health goals was critical to resource allocation; as Robin Gauld made clear in his analysis of New Zealand’s health reforms, area health boards were required by their contracts with the Minister of Health to ‘promote these goals and work towards continual improvements in health status’.<sup>10</sup> Nevertheless, even though public health officials regarded improvements in immunisation coverage as essential to preventing recurrent epidemics of vaccine-preventable diseases, the only goal specifically focused on child health was the reduction of hearing loss in preschoolers. Broader health priorities, such as smoking reduction, and reducing preventable death and disability from motor vehicle accidents, took precedence for policy attention.<sup>11</sup>

The decision to omit childhood immunisation from the health goals was even more striking when the low levels of immunisation coverage among New Zealand children were considered. By the late 1980s, the Health Department was aware that at least 30 per cent of New Zealand children missed out on their scheduled childhood immunisations.<sup>12</sup>

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<sup>7</sup> AJHR, 1990, E. 10, pp.4-5. As George Salmond, the Director-General of Health, noted, ‘The Department of Health [has been] restructured and downsized some 40 per cent to meet its new role at the centre of a public health system based on area health boards’. During 1989, Clark completed the transition from hospital boards, initiated in 1983 under the Area Health Boards Act, to area health boards. By December 1989, all 14 boards had been formed.

<sup>8</sup> *ibid.*

<sup>9</sup> The ten goals were: 1. To reduce smoking; 2. To reduce dietary-related disorders by improving nutrition; 3. To reduce alcohol-related health problems; 4. To reduce the prevalence of high blood pressure; 5. To reduce death and disability from motor vehicle accidents; 6. To reduce hearing loss among children under five; 7. To reduce death and disability from asthma; 8. To reduce illness and death from coronary heart disease and stroke; 9. To reduce the incidence of invasive cervical cancer and the cervical cancer death rate; 10. To reduce skin cancer (melanoma) incidence and death rates. Minister of Health, *New Zealand Health Charter*, ABQU 632 W4452/920 144/56/1 69888. For further discussion of the development of the first health goals, see for example, R. Beaglehole, P. Davis, ‘Setting national health goals and targets in the context of a fiscal crisis: The politics of social choice in New Zealand’, *International Journal of Health Services*, 22, 3, 1992, pp.417-28.

<sup>10</sup> R. Gauld, *Revolving Doors : New Zealand’s Health Reforms – The Continuing Saga*, p.65.

<sup>11</sup> Minister of Health, *New Zealand Health Charter*, ABQU 632 W445/920 144/56/1 69888.

<sup>12</sup> J. Jarman, ‘How can Immunisation Coverage in New Zealand be Improved?’, Project for Module F of the Diploma of Community Health, Wellington School of Medicine, 1990, private papers, J. Jarman; R.

While the Department had no means of accurately measuring immunisation coverage, immunisation benefit claims submitted to the Department by family doctors indicated that only 70 per cent of children received their routine immunisations. Moreover, in the mid-1980s, only 67 per cent of children were recorded as being fully immunised at school entry by public health nurses.<sup>13</sup> Studies conducted during the 1980s to identify those children most likely to miss out on immunisation produced varying results; however, research commissioned by the Department in 1989 suggested that caregivers who did not immunise their children were more likely to be of low socio-economic status, Maori, or Pacific.<sup>14</sup> The preliminary evaluation of the hepatitis B preschool campaign also revealed significant disparities between Maori and non-Maori immunisation rates.<sup>15</sup>

The selection of national health priorities appeared to provide the opportunity to reduce these differences and to concentrate resources on improving overall immunisation coverage. Why then was childhood immunisation left as a 'business as usual' preventive health programme? According to the criteria used to identify the health goals for the coming decade, improving immunisation coverage appeared to be an obvious choice for a sustained public health campaign.<sup>16</sup> The decision to leave immunisation off the list of national health goals also conflicted with the advice of senior health officials, who were aware that some countries, including the US, Sweden, and the Netherlands, had markedly improved immunisation coverage by measures such as increased infectious disease

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Lau, K. A. Bettelheim, A. C. Patel, 'The 1985 national immunisation survey: diphtheria, tetanus, and pertussis (whooping cough)', pp.797-800; M. Tobias, M., J. Scadden, C. J. Clements, A. C. Patel, 'Measles immunity in children: the 1985 national immunisation survey', pp.315-7.

<sup>13</sup> Department of Health, Circular Memorandum 1987/26, 'District Profiles 1986', cited in J. Jarman, 'How can Immunisation Coverage in New Zealand be Improved?', p.25.

<sup>14</sup> See for example, C. J. Clements, 'Diphtheria immunity in New Zealand children', NZMJ, 95, 23 June 1982, pp.422-3; M. Soljak, 'How many children are fully immunised?', NZMJ, 97, 25 January 1984, pp.37-9; M. Tobias, J. A. Miller, C. J. Clements, A. C. Patel, 'Hepatitis B in New Zealand children: the 1985 national immunization survey', pp.203-6. The research commissioned by the Health Department investigated caregivers' attitudes to immunisation. National Research Bureau, 'Attitudes to Immunisation', January 1990, ABQU 632 W4452/920 144/56/1 69888, ANZW.

<sup>15</sup> Health Services Research Delivery Unit, 'National Estimate of Compliance: Hepatitis B Immunisation Programme', draft report, June 1989, ABQU 632 W4452/704 131/171/4 66405.

<sup>16</sup> Minister of Health, *New Zealand Health Charter*, ABQU 632 W4452/920 144/56/1 69888.

surveillance and the use of national immunisation registers.<sup>17</sup> Further, during the late 1980s, immunisation coverage in developing countries was approaching the levels achieved in New Zealand as a result of initiatives introduced by the WHO Expanded Programme on Immunisation.<sup>18</sup>

In a memo to Clark in October 1989, Dr George Salmond, the Director-General of Health, had urged her to consider immunisation as one of the national health goals and targets.<sup>19</sup> Salmond, who put particular emphasis on the hepatitis B immunisation programme, suggested to Clark that area health boards should know what the Department's priorities were; 'what we are working on and what to expect'.<sup>20</sup> Nevertheless, Clark declined his advice. Her reasons for doing so are unclear; however, Gauld observed that she had a 'long-standing suspicion of bureaucracy'.<sup>21</sup> During her term as Health Minister (January 1989–October 1990), he described the Health Department as 'detached from the policy circuitry'. In 1989, external consultants 'were seconded to review administrative arrangements and advise the minister [and] the department was subsequently "informed" of the results and of new policy directions'.<sup>22</sup> When Clark announced priorities for child health later in 1990, immunisation did not rank highly.<sup>23</sup>

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<sup>17</sup> For example, in Sweden, overall coverage with the measles, mumps, and rubella vaccine improved from below 65 per cent between 1971 and 1981, to 93 per cent in 1985. This was attributed to a promotional campaign, the use of disease surveillance and regular surveys of children's immunity. In New Zealand, by contrast, uptake of the measles vaccine in 1986 was estimated to be 69 per cent. J. Jarman, 'How can Immunisation Coverage in New Zealand be Improved?', p.13; p.42.

<sup>18</sup> In 1988, the WHO reported a 67 per cent uptake of the polio vaccine and triple vaccine (diphtheria, whooping cough, and tetanus) in developing countries where the Expanded Programme of Immunisation was implemented. *ibid.*, pp.43-4.

<sup>19</sup> DGH to Minister of Health, 27 October 1989, 'National Health Goals/Targets', ABQU 632 W4452/1529 341/20/2 66977, ANZW.

<sup>20</sup> *ibid.*

<sup>21</sup> Gauld noted that even before entering politics Clark had written that 'government departments everywhere work to promote their own policies ... A department's pet policy can be indeed be a trap for the unwary minister'. H. Clark, 'Government and Decision-making for Social Change', in P. Davis, ed., *New Zealand Labour Perspectives: The Challenge of the Third Depression*, Auckland, 1981, cited in R. Gauld, *Revolving Doors: New Zealand's Health Reforms – the Continuing Saga*, p.63.

<sup>22</sup> *ibid.*, pp.63-4.

<sup>23</sup> Department of Health, 'Policy Statement: Priorities for Child Health Care in New Zealand', August 1990, cited in J. Jarman, 'How can Immunisation Coverage in New Zealand be Improved?', p.50.

While childhood immunisation was not prioritised as a health goal in the contracts between area health boards and the Minister of Health, boards were responsible for the delivery of the high risk hepatitis B programme. In early 1990, individual boards put their high risk proposals to the Health Department ‘to ensure that [they were] appropriate and the limited resources would be used in the most effective way’.<sup>24</sup> Although \$5.26 million had been approved by Cabinet for the delivery of the expanded hepatitis B immunisation programme, only \$316,000 had been earmarked for short term projects in ‘high risk areas’.<sup>25</sup> The high risk strategies were based on recommendations made by Communicable Disease Control Advisory Committee (CDCAC) in November 1989, which had advised boards to prioritise school children in ‘high risk communities’, specifically those attending ‘schools ... in lower socio-economic areas’.<sup>26</sup> While the inference was that immunisation initiatives should focus on Maori and Pacific children, boards were left to decide which children should receive extra attention and resources, and how the initiatives were to be delivered.<sup>27</sup>

Thus, universal childhood hepatitis B immunisation was introduced at the same time as structural changes to the Health Department, and a significant shift in policy focus. The *New Zealand Health Charter* set clear priorities for preventive health; however, despite the obvious failings of the childhood immunisation programme, it was not among the health goals selected for the 1990s. The ‘high risk’ initiatives provided a temporary solution to reaching children at most risk of acquiring hepatitis B, but without a sustained focus on immunisation, health officials had little confidence that coverage rates would improve in the long term.

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<sup>24</sup> Department of Health, Memorandum for the Minister of Health, ‘Hepatitis B Programme – High Risk Areas/Communities’, 2 February 1990, ABQU 632 W4452/705 131/171/4 69791, ANZW.

<sup>25</sup> Minister of Health, Memorandum for Cabinet Social Equity Committee, Hepatitis B, 6 November 1989, ABQU 632 W4452/704 131/171/4 66798.

<sup>26</sup> CDCAC Minutes, 2 November 1989, Ministry of Health Archives, Wellington.

<sup>27</sup> Boards with substantial Maori populations clearly took the CDCAC’s advice to mean that Maori children should be targeted. By early 1990, Tairāwhiti in the Gisborne region, and Manawatu/Wanganui, which had high Maori populations, had already begun to work with Maori tribal authorities to ensure higher vaccine uptake among Maori pupils. Some boards, like Wellington, had identified schools with high Maori and Pacific rolls as the focus for their high risk programmes. Boards in the South Island with relatively few Maori or Pacific communities intended to concentrate on those children who had missed out on the preschool programme. Department of Health, Memorandum for the Minister of Health, ‘Hepatitis B Programme – High Risk Areas/Communities’, 2 February 1990, ABQU 632 W4452/705 131/171/4 69791.

### **The Central Medical immunisation scheme**

By including hepatitis B vaccine on the childhood immunisation schedule, Health Minister Helen Clark had anticipated she would put an end to the privately-run hepatitis B immunisation schemes for school children that had proliferated during 1989. One of the more contentious schemes had been introduced by Central Medical, an Auckland-based medical practice, which had funded its immunisation activities by claiming substantial medical benefits from the Health Department.<sup>28</sup> The reappearance of Central Medical as a nationwide vaccine provider in early 1990 was therefore an unexpected turn of events.

As Chapter Six discussed, Central Medical had first come to the attention of the Health Department in mid-1989, when it introduced a free hepatitis B immunisation service for school children in South Auckland.<sup>29</sup> The company funded its service by claiming the \$16 General Medical Services benefit for each dose of vaccine given to each child enrolled in its programme. On account of the ‘extraordinarily high numbers’ of claims submitted by its director, Dr Rhys Cullen, the Health Department had delayed paying Central Medical while it investigated the claiming of individual medical benefits for what it considered to be ‘mass immunisation procedures’.<sup>30</sup> Cullen was not the only doctor to submit apparently excessive claims; part of Clark’s rationale for expanding the hepatitis B policy in 1990 had been to ‘curtail abuse of the General Medical Services Benefit by certain medical practitioners’.<sup>31</sup> From February 1990, when hepatitis B vaccine went ‘on the schedule’, doctors were limited to claiming the \$7.65 Immunisation Benefit each time a child was immunised.

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<sup>28</sup> DGH to Cullen, ‘General Medical Services Benefits’, 16 October 1989; Cullen to DGH, 23 October 1989, 30 October 1989, ABQU 632 W4452/707 131/171/4/2 75084, ANZW.

<sup>29</sup> Stephenson to Minister of Health, ‘Hepatitis B immunisation in Schools’, 23 June 1989, ABQU 632 W4452/703 131/171/4 66639.

<sup>30</sup> DGH to Cullen, ‘General Medical Services Benefits’, 16 October 1989; Harrington to Minister of Health, ‘Inquiry into Dr R Cullen’s GMS Claims’, 30 October 1989, ABQU 632 W4452/707 131/171/4/2 75084, ANZW.

<sup>31</sup> Minister of Health, Memorandum for Cabinet Social Equity Committee, ‘Hepatitis B’, 6 November 1989, ABQU 632 W4452/704 131/171/4 66798.

Despite the fiscal limits imposed by the new policy, however, Cullen clearly saw commercial potential in providing a school-based hepatitis B immunisation programme. In mid-December 1989, soon after Clark announced the expanded immunisation policy, Central Medical began canvassing schools around the country to gauge the level of interest in a free vaccine service.<sup>32</sup> Some school principals, who had been approached by two or more private hepatitis B vaccine providers in the previous year, were wary of the Central Medical proposal. In other schools, however, where parents had been unable or unwilling to support 'user pays' schemes, principals were keen to sign up. Moreover, public health workers in many regions saw advantages in the Central Medical programme, which they regarded as an effective means of reaching 'high risk' school children. By early 1990, Central Medical was confirmed as a vaccine provider for schools in Auckland, Waikato, Hawke's Bay, Taranaki, and Canterbury, and in correspondence with the Health Department, Cullen indicated that its programme was likely to involve 50,000 school pupils.<sup>33</sup>

In spite of its popularity in many parts of the country, however, Central Medical was not welcomed in all regions. In the Rotorua area, for instance, where Alexander Milne had gained strong support for his programme of pre-immunisation screening of local school children, the Central Medical proposal was firmly rejected. In correspondence with Dr Arvind Patel, the Manager of the Health Department's Communicable Diseases Unit, Milne claimed that area health board staff and schools in and around Rotorua regarded the overtures by Central Medical as an 'intrusion', and had turned to him for 'help'.<sup>34</sup> As Chapter Six discussed, Milne regarded the Central Medical scheme as a direct threat to his own plans to introduce school-based screening and immunisation in high-risk communities.<sup>35</sup>

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<sup>32</sup> Hotte to School Principals, 12 December 1989, ABQU 632 W4452/705 131/171/4 67517, ANZW.

<sup>33</sup> Cullen to Stephenson, 19 February 1990, ABQU 632 W4452/707 131/171/4/2 75084, ANZW. In 1989, Health Department officials had estimated that there were over 550,000 primary and secondary school children in New Zealand. Shaw to Minister of Health, 'Hepatitis B Immunisation Programme', 3 March 1989, ABQU 632 W4452/703 131/171/4 65315.

<sup>34</sup> Milne to Patel, 10 February 1990, ABQU 632 W4452/705 131/171/4 69791, ANZW.

<sup>35</sup> In March 1990, Milne wrote to Warren Thompson, Manager of the Health Department's Medicines and Benefits Unit, complaining that the Central Medical scheme had compromised his fundraising efforts in Ngaruawahia. Milne to Thompson, 23 March 1990, ABQU 632 W4452/707 131/171/4 75858, ANZW.



In response to Milne's challenge, Cullen provided pre-immunisation screening for schools that requested it.<sup>36</sup> From a financial perspective, this strategy was ill-considered; the Health Department refused to refund the costs of pre-immunisation screening on the basis that these were not required by government policy, and disputed payment of the immunisation benefit where children had been immunised by nurses without a doctor present. The unpaid claims put Central Medical under intense financial pressure. In April 1990, it went into financial receivership amid a flurry of negative publicity, some of which was generated by the tense confrontation between Cullen and the television crew during the TVNZ documentary, 'Surgery Showdown'.<sup>37</sup> Cullen directed his anger and frustration firstly at the Health Department, then at Milne, whom he had earlier accused of being 'a biased researcher, inflexible, unable to accept the opinions of others, and an "arsehole"'.<sup>38</sup> Milne was quick to defend himself, and to call for a government inquiry into what he described as a 'Health Department shambles'.<sup>39</sup>

The opportunities presented by the apparent vacuum in immunisation services were not lost on Milne, who saw an opening for the HBCP to step into schools where children were half-way through a course of hepatitis B vaccine. In the aftermath of the Central Medical collapse, he rang Clark's office to get her backing for the 'rescue plan' he wanted to initiate.<sup>40</sup> Unsurprisingly, Clark and Health Department officials had a different perspective from Milne on the Central Medical debacle. Warren Thompson, the Manager of the Benefits and Subsidies Unit, wrote to Clark that 'Sandy Milne has been active in promoting the notion that a substantial mess has been created and that he should be called in to clean [it] up. That is not the view taken by the department. The situation is not one of chaos.'<sup>41</sup> As Chapter Seven discussed, Clark was wary of Milne's push to

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<sup>36</sup> Cullen to Stephenson, 19 February 1990, ABQU 632 W4452/707 131/171/4/2 75084.

<sup>37</sup> TVNZ Archives, P95719, 'Frontline: Surgery Showdown', 15 April 1990.

<sup>38</sup> V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, p.54; Cullen to Milne, 14 September 1989, ABQU 632 W4452/707 131/171/4/2 75084, ANZW. Cullen remained a controversial figure in New Zealand medicine throughout the 1990s. In 2007, his medical registration was suspended by the Health Practitioners Disciplinary Tribunal. Decision No: 91/Med06/44P, online, available at: <http://www.hpdt.org.nz/portals/0/med0644pfindingsuspension.pdf> (2 May 2010).

<sup>39</sup> 'Dept in firing line over vaccinations', *Napier Daily Telegraph*, 27 April 1990.

<sup>40</sup> Milne to Clark, 18 April 1990, W4452/707 131/171/4/2 75084, ANZW.

<sup>41</sup> Department of Health Memorandum, Thompson to Minister of Health, 'Hepatitis B Immunisation Programme', 19 April 1990, ABQU 632 W4452/706 131/171/4 68138, ANZW.

promote hepatitis B screening as an integral part of the hepatitis B immunisation programme. While she admitted that ‘there had been changes made [to departmental procedures] because some entrepreneurs had been able to make money from the state by doing hepatitis B vaccinations’, Clark made it clear that family doctors, not the HBCP, would be stepping into the breach.<sup>42</sup>

The short-lived Central Medical programme highlighted both the ongoing public demand for school-based hepatitis B immunisation, and the unforeseen openings for private ventures to exploit the funding available under the expanded hepatitis B policy. The demise of Central Medical also exposed Milne’s determination to advance his screening agenda, despite strong opposition from Clark and senior Health Department officials.

### **Confusion amongst area health boards following the collapse of Central Medical**

The sudden collapse of Central Medical in mid-April 1990 had a major impact on the implementation of hepatitis B strategies for high risk children. The subsequent confusion over which children had been immunised and how many doses of vaccine they had received, demoralised public health workers and left some schools and parents less willing to engage in future hepatitis B initiatives.

In May 1990, Alexander Milne made several requests to meet with the Health Minister to discuss the ‘shambolic’ state of the hepatitis B immunisation programme. Clark declined, stating that she was ‘quite satisfied with the progress of the extended hepatitis B programme so far’.<sup>43</sup> On the ground, however, many area health boards were experiencing problems in implementing the high risk component of the immunisation programme. These difficulties were exacerbated in districts where boards had relied on Central Medical to provide a school-based vaccine service. On going into receivership in mid-April 1990, the company left few detailed records of its immunisation programme. Furthermore, in South Auckland and Waikato, where Milne had provided pre-immunisation screening in schools with high Maori rolls, public health workers found

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<sup>42</sup> ‘Clark dismisses charges over hepatitis scheme’, *Napier Daily Telegraph*, 28 April 1990.

<sup>43</sup> Minister of Health to Milne, 21 May 1990, ABQU 632 W4452/705 131/171/4 69791, ANZW.

that some parents were unsure as to whether their children had been screened, immunised, or both.

A preliminary evaluation of the high risk hepatitis B programme completed for the Health Department in late July 1990 concluded that ‘progress ... has been slower and more difficult than the boards expected’.<sup>44</sup> Interviews undertaken with area health board staff revealed the extent of the difficulties they faced. The coordinator of the South Auckland programme, for example, reported that there was ‘immense confusion caused by multiple providers and [screening] all being carried out in the same area at the same time ... the whole situation is a total mess as to who has done what’.<sup>45</sup> Similarly, in the Hamilton area, there was ‘major confusion ... and difficulty in determining which schools have had what ... [and this was] taking some time to sort out’.<sup>46</sup> Of concern to the future of the programme, the Central Auckland coordinator reported that the collapse of Central Medical was seen by the public as a ‘reflection on the health service ... Some parents, schools and staff have become demoralised and disenchanted with [the] hepatitis B [programme]’. As a consequence, some schools were ‘reluctant to have anything more to do with hepatitis B [immunisation]’.<sup>47</sup>

Adding to the confusion was the difficulty of determining which children were at high risk; the concept of risk was interpreted differently by those implementing the programme in different parts of the country. In the Waikato region, for example, the coordinator of the hepatitis B programme ‘assumed it meant Maori children, as “high risk” was not defined anywhere’, while in Canterbury high risk was seen as ‘Polynesian and Maori children (because of non-compliance, as well as any medical risk) ... [as well as] underprivileged/lower socioeconomic status Pakeha’.<sup>48</sup> In Gisborne, ‘because of the large Maori population, the whole population [was] regarded as high risk’, and in South Auckland, ‘no particular definition [for high risk] was being used ... because children in

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<sup>44</sup> Health Research Services, ‘Children at Risk of Hepatitis B: Evaluation of Area Health Board Targeting Strategies’, July 1990, ABQU 632 W4452/699 131/171/1 79717, ANZW.

<sup>45</sup> *ibid.*, p.16; p.18.

<sup>46</sup> *ibid.*, pp.6-7.

<sup>47</sup> *ibid.*, p.22.

<sup>48</sup> *ibid.*, p.4; p.12.

South Auckland are the same population and have the same risk'.<sup>49</sup> The evaluation report concluded that 'the complexity of identifying and reaching high risk children' had been a hurdle in completing this component of the immunisation programme.<sup>50</sup>

The muddled situation wasted time and resources that might otherwise have been spent on immunising high-risk children. Throughout the interviews with staff from four area health boards, the report noted that 'The sustained and concentrated effort required simply to identify the immunisation status of children was repeatedly emphasised.' Several participants also expressed concern at the effect on staff morale.<sup>51</sup> Of critical importance, in areas where Central Medical had been involved, boards had not applied for extra funding for the next financial year, believing that Central Medical would deliver much of the required programme. As a consequence, by the time boards became aware that extra funds were needed, resources were no longer available.<sup>52</sup>

By July 1990, six months into the high risk hepatitis B programme, it appeared that little progress had been made on immunising high risk children in most area health boards with significant Maori populations. Of the five boards assessed, only the Tairāwhiti Area Health Board in the Gisborne region, which had moved quickly to prevent Central Medical entering its area, had achieved its objectives. Tairāwhiti had contracted a group of local family doctors to give hepatitis B immunisations in schools, and expected to complete its high risk programme by the end of 1990. The Tairāwhiti programme, which intended to computerise its immunisation records and evaluate immunisation rates, gave some indication of what could have been achieved in other areas, had the high risk hepatitis B initiatives gone to plan.<sup>53</sup>

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<sup>49</sup> *ibid.*, p.7; p.15.

<sup>50</sup> *ibid.*, p.4.

<sup>51</sup> *ibid.*, p.2.

<sup>52</sup> *ibid.*, p.5.

<sup>53</sup> *ibid.*, p.2; p.10.

### **Support for Milne's high risk programme**

Despite his uneven relationship with Helen Clark and the Health Department, Alexander Milne found strong support for his approach to hepatitis B immunisation for 'high risk' children among Maori health professionals and senior members of the Maori community. As Chapter Seven discussed, this support was partly predicated on the promise of a low cost herbal treatment for hepatitis B carriers, and partly on the basis that identified carriers would receive counselling and education, and that their close contacts could be immunised against the disease.

During the first half of 1990, in correspondence with the Health Department, Milne described the HBCP as 'very active' in North Island schools in 'high risk' communities.<sup>54</sup> After concentrating on the Rotorua district and the Eastern Bay of Plenty region, Milne made arrangements to enter schools in high risk areas of Auckland and Northland. By August 1990, the HBCP had screened children in over 150 schools from Kaitaia to Napier and immunised those children who were susceptible to hepatitis B.<sup>55</sup> While Milne had strong support from Maori, however, his activities did not comply with official Health Department policy, and he created some antipathy among public health officials as a result of his extensive screening and immunisation programme.<sup>56</sup>

In June 1990, Dr John Crawford, the Health Department's Principal Medical Officer for Benefits and Subsidies, asked Milne to address 'factual and interpretative errors' in the written material that the HBCP provided for schools. Crawford clearly considered Milne's assertion that the HBCP would 'claim the \$16 General Medical Services benefit for each child screened for hepatitis B' fell outside departmental guidelines: 'This letter is

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<sup>54</sup> Milne to Patel, 13 July 1990, 'Hepatitis B carriers in schools', ABQU 632 W4452/706 131/171/4 69791, ANZW.

<sup>55</sup> In August 1990, Milne sent Arvind Patel, the Manager of the Department's Communicable Diseases Unit, an impressive list of the primary schools and colleges the Hepatitis B Control Programme had already covered. Milne to Patel, 10 August 1990, ABQU 632 W4452/706 131/171/4 74976, ANZW.

<sup>56</sup> Milne also had support from Maori within the state sector; in correspondence with Helen Clark, Milne informed her that staff from Manatu Maori, and members of the Health Department's Maori Health Unit, had visited the HBCP in schools. Milne to Minister of Health, 14 August 1990, ABQU 632 W4452/706 131/171/4 69791, ANZW.

to advise you on what is improper claiming and [what] may be considered an offence'.<sup>57</sup> Further, in correspondence with Arvind Patel, the Manager of the Department's Communicable Diseases Unit, in early October 1990, Dr Lester Calder, a community medicine registrar in South Auckland, asked who was expected to provide short-term follow up for carriers identified by the HBCP, including the immunisation of household contacts, and the education and counselling of carriers and their families. Calder was wary of Milne's ability to sustain these aspects of the screening programme: '[Milne] invites us to "take an interest in the household contact follow-up". Does this mean he cannot do it?'<sup>58</sup>

Nevertheless, despite the friction between Milne and public health officials, his approach had strong support among Maori and among opposition politicians in some North Island electorates. In the general election in late October 1990, National was returned to power after Labour suffered a resounding defeat at the polls. Simon Upton, the Minister of Health, and Winston Peters, the Minister of Maori Affairs, were both sympathetic to Milne's campaign for pre-immunisation screening. Upton represented Raglan, a rural constituency with a large Maori population, and Peters, who represented Tauranga, professed to have 'have supported [Milne's] programme since its inception'.<sup>59</sup>

In early November 1990, Upton met with Milne and Health Department officials to discuss issues that had arisen over the validity of medical benefits claims submitted by the HBCP. Following the meeting, Ian Millar, General Manager of Services, provided Upton with a summary of events.<sup>60</sup> Millar indicated that while payments had been made to the HBCP for screening and immunising high risk school children earlier in 1990, this was during a period when the Department was experiencing 'extreme pressures' with the introduction of a new financial management system. He advised Upton that the situation

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<sup>57</sup> Crawford to Milne, 21 June 1990, ABQU 632 W4452/707 131/171/4 75858, ANZW.

<sup>58</sup> Calder to Patel, 5 October 1990, ABQU 632 W4452/707 131/171/4 75858, ANZW.

<sup>59</sup> Peters to Upton, 'Hepatitis B in Maori children', 16 November 1990, ABQU 632 W4452 W4452/707 131/171/4 75858, ANZW. In his letter to Upton, Peters described the identification of hepatitis B carriers to be 'on the face of it ... a logical first step in any [hepatitis B] control programme'.

<sup>60</sup> Department of Health Memorandum, Millar to Minister of Health, 'NZ Hepatitis B Programme Payment of Medical Benefits', 8 November 1990, ABQU 632 W4452/705 131/171/4 69791, ANZW.

was more complex than it first appeared, and that even though Milne's activities had increased the number of Maori and Pacific children protected against hepatitis B, they challenged official hepatitis B immunisation policy:

You have the authority to make special arrangements for payment [of these claims] ... There are however two difficulties: In the first instance to pay under this provision would effectively change the established policy on hepatitis B [which is] based on mass immunisation, not on mass screening. This policy was based on independent expert advice which Mr Milne does not accept. In the second place it would be very difficult to establish just what should be paid. The Milne scheme has grown to the level it has by unusual means and to now reward inappropriate claiming would seem difficult to justify.<sup>61</sup>

Despite Millar's cautionary views on Milne's programme, however, Upton remained convinced of its merits. From Upton's perspective, Milne's direct approach to immunising 'high risk school children' undoubtedly appeared more effective than the Department's uncoordinated attempts to reach children in 'high risk communities'. Background papers outlining government policies for hepatitis B only served to emphasise the low uptake of vaccine among Maori children during the 1988 preschool immunisation campaign, while the difficulties encountered by area health boards in 1990 provided little assurance that public health strategies had improved in the intervening period.<sup>62</sup>

In early December 1990, Health Department officials presented Upton with two options for the implementation of a 'more effective' programme for hepatitis B control in high risk communities. These were: initiatives designed and delivered by individual area health boards, or a programme carried out by a contracted provider, in much the same way as the Plunket Society was contracted to provide child health services for the Health Department. Officials stated a clear preference for the second option: 'The Whakatane

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<sup>61</sup> *ibid.*

<sup>62</sup> Department of Health, 'Hepatitis B Immunisation Programme', 12 November 1990, ABQU 632 W4452/705 131/171/4 69791; Department of Health, 'Immunisations in General', 12 November 1990, ABQU 632 W4452/920 144/56/1 69888, ANZW.

Trust has experience in the management of a hepatitis B control programme and would obviate the need for boards to develop programmes independently'. Not only that, but the Health Department was aware that a number of area health boards were struggling to implement high risk immunisation strategies in their regions.<sup>63</sup>

Although no funding had been allocated to maintain the high risk component of the hepatitis B programme in 1991, Upton used his powers under Sections 117 and 118 of the 1964 Social Security Act to change the basis on which health benefits were paid, so that payments could be made to the Whakatane-based Hepatitis Control Trust from funding set aside for health benefits.<sup>64</sup> From March 1991, when Upton signed the first contract with the Trust, until 1994, Milne provided a screening and immunisation service targeting North Island schools with high Maori and Pacific rolls. Upton described Milne's programme as a 'complement to existing immunisation delivery through general practitioners'.<sup>65</sup> Even so, he restricted funding for the scheme to \$1.5 million; like his predecessor Helen Clark, Upton regarded 'stand alone' high risk programmes as short-term preventive health interventions.

A change of government, as well as Milne's determined efforts to promote the benefits of screening among high risk children enabled him to secure government support and funding for his targeted screening and immunisation programme. While health officials were wary of delegating responsibility for the 'high risk' hepatitis B programme to Milne and the HBCP, they were also aware that in the aftermath of the collapse of Central Medical, many area health boards were ill-equipped to deliver targeted immunisation initiatives.

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<sup>63</sup> Department of Health Memorandum, Johns to Minister of Health, 'Hepatitis B Control Programme for High-Risk Communities/Areas', 5 December 1990, ABQU 632 W4452/700 131/171/1/2 69340, ANZW.

<sup>64</sup> Hawkins to Minister of Finance, 'Hepatitis B Immunisation Programme', 21 December 1990, ABQU 632 W4452/707 131/171/4 75858, ANZW. The Hepatitis B Control Programme (HBCP) became the Hepatitis Control Trust (HCT) in 1991 to undertake its contract with the Health Department.

<sup>65</sup> Minister of Health, News Release, 'New programme targets high risk hepatitis B communities', ABQU 632 W4452/699 131/171/1 76901, ANZW.



## Linking hepatitis B control to broader immunisation issues

Health Department officials saw the problems highlighted by the hepatitis B programme in the context of the wider issues impacting on the delivery of all vaccines on the national immunisation schedule. While they were in favour of short-term immunisation strategies such as the public health initiatives targeting children at high risk of hepatitis B virus infection, they considered it essential to improve immunisation coverage overall to control hepatitis B and other vaccine-preventable diseases in the long term.

The childhood hepatitis B immunisation programme came under close scrutiny in late 1990 with the completion of four evaluation studies.<sup>66</sup> These studies assessed the conduct of the preschool campaign, the efficacy of ‘low dose’ hepatitis B vaccine, the effectiveness of the ‘high risk’ strategies used by area health boards, and the process followed by area health boards to ensure the babies of carrier mothers were protected against hepatitis B.<sup>67</sup> They drew attention to the difficulties of identifying and reaching children at high risk of the disease, and the low uptake of the hepatitis B vaccine among Maori and Pacific children, despite the investment of significant public health resources.<sup>68</sup> As the children who missed out on hepatitis B immunisation broadly equated to those who missed out on other vaccines, health officials argued that the issues revealed

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<sup>66</sup> Health Research Services, ‘Hepatitis B Preschoolers Immunisation Campaign (1988/1989) Process Evaluation’, September 1990, ABQU 632 W4452/705 131/171/4 69791; A. Milne, C. D. Moyes, J. Waldon, N. E. Pearce, S. Krugman, ‘Mass vaccination against hepatitis B in preschool children: immunogenicity after three reduced doses’, NZMJ, 102, 23 August 1989, pp.429-30; C. D. Moyes, A. Milne, J. Waldon, ‘Very low dose hepatitis B vaccination in the newborn: anamnestic response to booster at four years’, *Journal of Medical Virology*, 30, 1990, pp.216-8; Health Research Services, ‘Children at Risk of Hepatitis B: Evaluation of Area Health Board Targeting Strategies’, July 1990, ABQU 632 W4452/699 131/171/1 79717; Health Services Research and Development Unit, ‘Vaccination Programme for Carrier Mothers: Process Evaluation of the Hepatitis B Immunisation Programme for Children born to Carrier Mothers (1989/90)’, July 1989, ABQU 632 W4452 1951 372/21/6 73274, ANZW.

<sup>67</sup> Department of Health, Communicable Diseases Unit, ‘Hepatitis B: A Review’, December 1990, ABQU 632 W4452/699 144/56/1 76900, ANZW. In 1990, a further evaluation study was in progress on the infant immunisation programme in Northland. Preliminary data also showed marked ethnic disparities in vaccine uptake. C. Salmond, D. Bandaranayake, ‘Progress of the neonatal hepatitis B immunisation programme in Northland’, NZMJ, 104, 12 June 1991, p.233.

<sup>68</sup> Department of Health, Communicable Diseases Unit, ‘Hepatitis B: A Review’, December 1990, ABQU 632 W4452/699 144/56/1 76900. Health officials emphasised that both the preschool immunisation programme and the study of Northland infants ‘employed a more rigorous system of follow up reminders than is ... used for other vaccines on the immunisation schedule’.

by the hepatitis B programme indicated that new approaches to vaccine delivery were required for all immunisations on the childhood schedule.<sup>69</sup>

In February 1991, Department officials outlined a series of ‘strategic options’ for improving immunisation coverage among New Zealand children.<sup>70</sup> They were in no doubt that improvements were required; they gave the ‘most optimistic estimate of immunisation coverage overall’ at the age of two years as 70 per cent, but ‘believed that the coverage levels in many high risk communities, such as Maori and Pacific Islander groups ... could be as low as 40 per cent’. They also acknowledged that there was a ‘small but growing’ number of parents who refused to have their children immunised as a result of ‘a dangerous perception that immunisation is unnecessary ... and that the benefits of disease prevention are outweighed by the risk of adverse reactions’. However, this group was considered to be of lesser concern; the greater problem was seen in the delivery of immunisation to children from lower socio-economic groups, primarily ethnic minorities.<sup>71</sup>

While family doctors administered the majority of immunisations, the Health Department recommended that ‘alternative [vaccine] delivery mechanisms’ be developed to encourage uptake among Maori and Pacific children.<sup>72</sup> In late 1990, members of the Department’s Maori Health Unit had proposed that a marae-based immunisation programme be piloted, to give parents and caregivers the opportunity to take ‘ownership of the responsibility for immunisation’.<sup>73</sup> Consultation with both Maori and Pacific representatives supported the concept of community-based health programmes that complemented general practices, by offering ‘well child’ checks along with immunisations and health education.<sup>74</sup> This was considered particularly important in

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<sup>69</sup> *ibid.*

<sup>70</sup> Department of Health, ‘Immunisations Strategic Options’, 8 February 1991, ABQU 632 W4452/920 144/56/1 69888, ANZW.

<sup>71</sup> *ibid.*

<sup>72</sup> *ibid.*

<sup>73</sup> Department of Health, ‘Proposal for Effective Immunisation Uptake’, 15 November 1990, ABQU 632 W4452 2081 194/34/1 2, ANZW.

<sup>74</sup> Department of Health, ‘Immunisations Strategic Options’, 8 February 1991, ABQU 632 W4452/920 144/56/1 69888.

view of the 1990 survey on caregivers' attitudes to immunisation in which 14 per cent of Maori and 24 per cent of Pacific participants believed that there was a fee involved with immunisations administered by family doctors.<sup>75</sup>

The 1990 survey, which revealed low levels of awareness with regard to immunisation, emphasised the importance of knowledge and beliefs in motivating parents and caregivers to immunise their children.<sup>76</sup> Equally, a project undertaken among Maori mothers in South Auckland in 1990 reinforced the need for a more intensive focus on consumer education. These mothers, who complained of receiving conflicting advice from friends, relatives, and health care workers, expressed a 'greatly reduced' interest in immunisation once their children reached 12 to 15 months of age. Television was suggested as the most effective medium for reaching groups such as these, who spent a 'considerable amount of time at home watching television'.<sup>77</sup> In response to these findings, the Health Department recommended a 'multi-faceted' immunisation awareness campaign focused on parents, caregivers, and health professionals.<sup>78</sup>

More controversially, the Department also recommended that immunisation be made a requirement for entry to preschool and primary school by the beginning of the 1993 school year. 'Mandatory parental choice', a system whereby documented evidence of immunisation was required before a child was accepted into a school environment, was already in place in 18 countries worldwide, including the US, and had recently been introduced in the State of Victoria, Australia.<sup>79</sup> The success of the US measles immunisation programme was widely attributed to its mandatory immunisation system.<sup>80</sup> However, this proposal, which had strong backing from the Communicable Disease

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<sup>75</sup> National Research Bureau, 'Attitudes to Immunisation', January 1990, ABQU 632 W4452/920 144/56/1 69888.

<sup>76</sup> *ibid.*

<sup>77</sup> Department of Health, 'Notes of the Immunisation – Future Strategic Planning Group', 16 October 1990, ABQU 632 W4452/920 144/56/1 69888, ANZW.

<sup>78</sup> Department of Health, 'Immunisations Strategic Options', 8 February 1991, ABQU 632 W4452/920 144/56/1 69888.

<sup>79</sup> Under a 'mandatory choice' system, parents could refuse to immunise their child, but they would be required to sign a document to that effect. Children could also be exempted from mandatory immunisation on medical grounds.

<sup>80</sup> J. Jarman, 'How can Immunisation Coverage in New Zealand be Improved?', p.50.

Control Advisory Committee (CDCAC), was less likely to win the support of the New Zealand public.<sup>81</sup> As Alison Day explained in her 2008 PhD thesis on the reactions and responses to childhood immunisation in New Zealand, in the 1980s there had been ‘a rebirth of organised objection to immunisation ... [and] it had become more commonplace for people to question health professionals ... rather than accepting what they were told’.<sup>82</sup> Nevertheless, the Department considered ‘mandatory choice’ to be an effective strategy for improving coverage rates, especially among those children who were most likely to miss out on their scheduled immunisations.<sup>83</sup>

In accordance with the ‘health ‘goals and targets’ introduced by the previous Labour administration, the Health Department also proposed the introduction of a national target for immunisation coverage. For the first time, prior to the introduction of the measles, mumps, and rubella (MMR) vaccine in late 1990, the Department had included an uptake target in its planning strategy. This target had been set at 90–95 per cent by 1995 for all children aged five years.<sup>84</sup> Despite the conspicuous gap between the estimates of immunisation coverage and the projected target, health officials considered it to be a realistic objective provided immunisation was included as a priority issue in the area health board contracts for 1991–1992.<sup>85</sup> This view was shared by area health board staff, who agreed that unless childhood immunisation was prioritised in their annual contracts, ‘it [would be] hard for the activity to be given a high profile’.<sup>86</sup>

Monitoring progress towards a coverage target required more accurate data, and as discussed earlier in this chapter, in 1990 the Health Department had no reliable systems

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<sup>81</sup> CDCAC minutes 6 December 1990, Ministry of Health Archives; Reid to Minister of Health, 24 June 1991; Associate Minister of Health to Reid, 29 July 1991, ABQU 632 W4452/918 144/56 79608, ANZW.

<sup>82</sup> A. S. Day, ‘Child Immunisation: Reactions and Responses to New Zealand Government Policy 1920 – 1990’, pp.291-2.

<sup>83</sup> In a system of ‘mandatory choice’, at preschool and school entry, children with incomplete immunisation records would be offered ‘catch up’ immunisations with parental consent.

<sup>84</sup> Department of Health, ‘Immunisations in General’, 12 November 1990, ABQU 632 W4452/920 144/56/1 69888, ANZW. In this document, the Department explained that ‘It has not been routine policy to provide specific immunisation coverage targets as part of the national immunisation programme’.

<sup>85</sup> *ibid.*; Department of Health, ‘Immunisations Strategic Options’, 8 February 1991, ABQU 632 W4452/920 144/56/1 69888.

<sup>86</sup> *ibid.*

for recording vaccine uptake.<sup>87</sup> The introduction of a computerised national immunisation register was described as having ‘enormous’ financial implications, but immunisation coverage surveys presented a cost-effective alternative.<sup>88</sup> In early 1990, responsibility for immunisation surveillance had been transferred from the Health Department’s Communicable Diseases Unit to the New Zealand Communicable Disease Centre (NZCDC). While the NZCDC was developing a range of surveillance initiatives, the Health Department recommended that a coverage survey would suffice to provide reliable data on vaccine uptake among New Zealand children in the short-term.<sup>89</sup>

It is clear then, that the failings of the hepatitis B immunisation programme were an important factor in the drive to improve overall uptake of the vaccines on the childhood immunisation schedule. Health officials regarded the striking ethnic disparities in immunisation rates as representative of the childhood programme as a whole, and as an incentive to develop more innovative ways of delivering vaccine services to those children who were missing out on their scheduled immunisations.<sup>90</sup>

### **Obstacles to improving immunisation coverage in the 1990s**

The change of government in late 1990 resulted in a radical reform of the public health system. In an attempt to contain and reduce health expenditure, the National Government introduced major changes to the funding, purchasing and provision of public health services.<sup>91</sup> While immunisation was established as a priority for child health during the National administration (1990–1996), successive health ministers proved reluctant to provide the high-level advocacy and additional resources required to improve coverage levels. Moreover, the restructuring of the health sector proved to be a major distraction for the Health Department.

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<sup>87</sup> *ibid.* Health officials concluded that ‘The lack of accurate data makes it almost impossible to establish coverage targets for specific immunisations.’

<sup>88</sup> Patel to Nichol, ‘Promoting the Health of New Zealand Children’, 19 April 1991, ABQU 632 W4452/918 144/56 79608, ANZW.

<sup>89</sup> Department of Health, ‘Immunisations in General’, 12 November 1990, ABQU 632 W4452/920 14456/1 69888.

<sup>90</sup> *ibid.*

<sup>91</sup> See for example, M. Laugesen, ‘Why some market reforms lack legitimacy in health care’, *Journal of Health Politics, Policy and Law*, 30, 6, December 2005, pp.1065-1100; R. Gauld, *Revolving Doors: New Zealand’s Health Reforms – the Continuing Saga*, pp.78-81.

Within weeks of taking office in late October 1990, the new National Government signalled its intention to ‘radically reshape’ the public health services.<sup>92</sup> Faced with a fiscal crisis, the Prime Minister, James (Jim) Bolger, indicated that substantial reductions in health spending would be required, and that a market-oriented system of health care would prevail.<sup>93</sup> While no immediate changes were implemented, the Health Minister Simon Upton appointed a ministerial taskforce to develop recommendations for re-configuring the public health system, and to provide guidance to the Government on the future direction of the health services. No aspect of the health sector was to be exempt from the upheavals of the reform process; in early 1991, as the Health Department braced itself for yet another major restructure, the Director-General of Health, Dr George Salmond, resigned.<sup>94</sup>

With the increased emphasis on cost containment, public health officials ranked their recommendations for improvements to the immunisation programme on a financial basis. In February 1991, Upton was presented with low, medium, and high cost strategies to raise immunisation coverage among two year old children to the target level of 95 per cent by 1995.<sup>95</sup> While the recommendations listed as ‘low cost’ were described as ‘essential’, health officials acknowledged that they would not be sufficient to substantially improve immunisation coverage. At least \$2.4 million of extra funding would be needed to cover the costs of a broad-based immunisation awareness campaign, as well as the purchase of the extra vaccine and the additional immunisation benefit claims that would result if immunisation gained a higher public profile.<sup>96</sup> Further analysis of these costs by the Department’s Benefits and Subsidies Unit suggested even greater expenditure if immunisation coverage improved by ten per cent in the coming year.<sup>97</sup>

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<sup>92</sup> M. Laugesen, G. Salmond, ‘New Zealand health care: a background’, p.15.

<sup>93</sup> R. Gauld, *Revolving Doors: New Zealand’s Health Reforms – the Continuing Saga*, pp.79-81.

<sup>94</sup> *ibid.*, p.78. Salmond’s successor, Christopher Lovelace, a Canadian, did not arrive in New Zealand until 1992.

<sup>95</sup> Kill to Minister of Health, ‘Immunisation Strategic Options: Report of the Department of Health Immunisation Working Group’, 8 February 1991, ABQU 632 W4452 2081 194/34/1 2, ANZW.

<sup>96</sup> *ibid.*

<sup>97</sup> Thomson to Minister of Health, 15 February 1991, ABQU 632 W4452 918 144/56 79608, ANZW.

The heightened sensitivity to the costs of preventive health was obvious in official statements on the immunisation programme. For example, in an address to the Waikato Division of the New Zealand Medical Association in April 1991, the Associate Minister of Health, Katherine O'Regan, spoke of the 'huge' Government investment in immunisation.<sup>98</sup> While she referred to the Health Department's strategic options for improving immunisation coverage, she cautioned that 'the deliberations from Government's health task-force [would] determine to a large extent the future direction of policy on health funding'.<sup>99</sup> Nevertheless, in early 1991 Upton took the first step towards implementing the Department's recommendations by asking the NZCDC to gather accurate information on immunisation rates as a basis for future policy development and resource allocation.<sup>100</sup> Moreover, he approved a departmental proposal to contract the Maori Women's Welfare League to develop a pilot immunisation project for Maori infants in South Auckland.<sup>101</sup>

In mid-1991, the NZCDC initiated the first national immunisation coverage survey in New Zealand.<sup>102</sup> The results of this survey, published in 1992, confirmed the need to improve immunisation coverage, especially among Maori and Pacific children. While overall coverage at two years of age was 56 per cent, only 42 per cent of Maori children and 45 per cent of Pacific children were fully immunised by this time.<sup>103</sup> Furthermore, the NZCDC reported that the number of children who received their immunisations on

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<sup>98</sup> O'Regan stated that \$6.1 million was spent from 1989 to 1990 on the purchase of vaccine and the payment of immunisation benefits, and that this did not include the resources spent by area health boards on immunisation. Associate Minister of Health, Address to the Waikato Division of the New Zealand Medical Association, 9 April 1991, ABQU 632 W4452 918 144/56 79608, ANZW.

<sup>99</sup> *ibid.*

<sup>100</sup> Stehr-Green to Talbot, 'Regional Immunisation Coverage Surveys', 2 December 1991, ABQU 632 W4452 2081 194/34/1 2, ANZW.

<sup>101</sup> Department of Health, 'Minutes of Meeting between Representatives of the Maori Women's Welfare League and the Department of Health: Friday 15<sup>th</sup> March 1991', ABQU 632 W4452/707 131/171/4 75858, ANZW; Johns to Minister of Health, 'Proposal for a Targeted Immunisation Promotion Pilot Project', 7 May 1991, ABQU 632 W4452 2081 194/34/1 2, ANZW. The South Auckland pilot led to two further pilot projects in Auckland and in the Bay of Plenty in 1993. M. Durie, *Whaiora: Maori Health Development*, p.204.

<sup>102</sup> P. Stehr-Green, 'How well are we protecting our children? The need for regional immunization coverage surveys', CDNZ, 91, 9, September 1991, pp.83-8. The New Zealand survey was based on the model developed by the WHO Expanded Programme on Immunization.

<sup>103</sup> NZCDC, 'Immunisation coverage in New Zealand: Results of the regional immunization coverage surveys'.

the scheduled date was ‘distressingly low’, resulting in children remaining at ‘heightened risk of infection with potentially life-threatening diseases for an unnecessarily prolonged period’.<sup>104</sup> ‘On time’ immunisation had particular relevance for hepatitis B control, as babies and young children infected by the virus were more likely to develop chronic hepatitis B carriage.

The results of the NZCDC study were corroborated by a 1992 survey of almost 1600 babies born in the Eastern Bay of Plenty between the beginning of 1989 and the end of 1990.<sup>105</sup> Overall, 57 per cent of two year old children had completed the recommended immunisation schedule, however, in an ‘industrial town of mixed race’ (presumably Kawerau, the site of the first community-funded hepatitis B immunisation programme), only 38 per cent of two year old children had been fully immunised.<sup>106</sup> The marked decline in immunisation coverage during the first year prompted Dr Chris Moyes, a co-author of the survey and a close collaborator of Alexander Milne, to lobby the CDCAC to alter the timing of the third dose of hepatitis B vaccine from fifteen months to five months of age. Moyes argued that a drop-off in immunisation coverage over the first year was even more likely among Maori and Pacific children, who were also at high risk of acquiring hepatitis B virus infection.<sup>107</sup>

In 1992, childhood immunisation was named as one of six pilot health goals by the National Government.<sup>108</sup> While the original health goals framework had been abandoned for a new approach to health policy, the concept had been retained, and clear goals for improvements in immunisation coverage were put in place. Nevertheless, the immunisation target set for two year old children by the Health Department in 1990 was noticeably downscaled, from ‘95 per cent of children by 1995’ to ‘80 per cent by the year

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<sup>104</sup> *ibid.*, p.10.

<sup>105</sup> D. Ramadas, C.D. Moyes, G. Ramadas, ‘Immunisation status of children in the eastern Bay of Plenty’.

<sup>106</sup> *ibid.*

<sup>107</sup> CDCAC minutes, 19 September 1991 and 2 March 1992, Ministry of Health Archives, Wellington. In 1996, the third dose of hepatitis B vaccine was brought forward from fifteen to five months of age to give early protection to infants. Ministry of Health, *Immunisation Handbook 2002*, Wellington, 2002, p.69.

<sup>108</sup> Public Health Commission (PHC), ‘Health goals’, *New Zealand Health and Hospital*, 44, 6, November – December 1992, p.6.



1995, and to 90 per cent by the year 2000'.<sup>109</sup> Despite the obvious need to implement focused strategies to improve vaccine uptake, however, no action was taken. Other priorities took precedence; throughout 1992 the Health Department was preoccupied by the restructuring of the health services, a major measles epidemic, and a controversial inquiry into the introduction of blood testing for hepatitis C.<sup>110</sup> In addition, Upton was replaced in early 1993 by a senior National politician, William (Bill) Birch, who was himself replaced as Health Minister after the 1993 election by Jenny Shipley.<sup>111</sup>

In July 1993, the Health Department became the Ministry of Health. As part of the health reforms, its responsibilities for public health regulation and health promotion were shared with a newly established agency, the Public Health Commission (PHC), which was charged with 'improving and protecting the public health and meeting the Crown's objectives for public health'.<sup>112</sup> In 1993, the PHC convened an expert working group on immunisation, and in 1994, provided advice to the Health Minister, Jenny Shipley, on improving immunisation coverage.<sup>113</sup> The PHC's recommendations included the development of a national information system on immunisation coverage, greater coordination of the immunisation programme at national, regional, and local levels, and the provision of culturally appropriate immunisation services.

Provided the full range of its recommendations was adopted, the PHC anticipated that immunisation coverage among two year old children would rise to 85 percent by the year 1997, and to 95 percent or more by the year 2000. Moreover, it was confident that

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<sup>109</sup> PHC, *Report of the Expert Working Group to the Public Health Commission on the National Immunisation Strategy*, Wellington, 1993. For further discussion of the development of the New Zealand health goals framework see for example, L. Signal, G. Durham, 'A case study of health goals in New Zealand', *Australian and New Zealand Journal of Public Health*, 24, 2, April 2000, pp.192-7.

<sup>110</sup> The 1991 measles epidemic was the largest ever recorded in New Zealand. It affected an estimated 30,000 children, with 640 children admitted to public hospitals and six deaths attributed to the disease. M. Baker, 'The 1991 measles epidemic in New Zealand', National Immunisation Conference, Melbourne, 1993, cited in M. Tobias, S. Christie, O. Mansoor, 'Predicting the next measles epidemic', *New Zealand Public Health Report*, 4, 1, January 1997, pp.1-3.

<sup>111</sup> The 1993 general election was held on 6 November 1993.

<sup>112</sup> PHC, *Report of the Expert Working Group to the Public Health Commission on the National Immunisation Strategy*; PHC, *Immunisation: The Public Health Commission's Advice to the Minister of Health 1993-1994*, Wellington, 1994.

<sup>113</sup> *ibid.*, p.3.

coverage among Maori would be improved to match the non-Maori rate by 1997.<sup>114</sup> In terms of the increased resources required to achieve such dramatic improvements in coverage, the PHC pointed to the direct costs of the 1991 measles epidemic for the health services and for families, estimated at between \$5 and \$8 million: ‘On the basis of preventing just one of the eight diseases in the national schedule the extra expenditure is justified’.<sup>115</sup>

As it was, few of the PHC’s recommendations on immunisation were implemented. Instead, Shipley called for further work on the immunisation policy. Quite apart from its advice on immunisation, Shipley had broader concerns about the PHC’s approach to its broader role and function; as Gauld explained, she perceived the ‘arms-length relationship’ it had adopted towards the Government as ‘unsuitable for the principal [policy] adviser to the Health Minister and to Cabinet’.<sup>116</sup> In December 1994, she disbanded the PHC and returned responsibility for the public health services to the Ministry of Health.<sup>117</sup>

The loss of the PHC, which had described itself as ‘an agency ... responsible for the achievement of high immunisation coverage’, removed a key source of support for childhood immunisation.<sup>118</sup> During the PHC’s brief tenure, the Communicable Disease Control Advisory Committee (CDCAC) had been replaced by a committee with the same name, to provide the PHC with scientific and technical advice on public health matters.<sup>119</sup> While the CDCAC produced the first New Zealand *Immunisation Handbook* during this period, the dissolution of the PHC undoubtedly disrupted its advocacy role.<sup>120</sup> Moreover,

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<sup>114</sup> *ibid.*, p.8.

<sup>115</sup> *ibid.*

<sup>116</sup> R. Gauld, *Revolving Doors: New Zealand’s Health Reforms – the Continuing Saga*, p.119.

<sup>117</sup> In *Public Health at the Crossroads: Achievements and Prospects*, 2<sup>nd</sup> edn, Cambridge 2004, p.218, authors Robert Beaglehole and Ruth Bonita argued that the underlying reason for the demise of the PHC was its semi-independent status, and its ‘tendency to provide the government with advice contrary to the powerful health-damaging interests in New Zealand’.

<sup>118</sup> *Report of the Expert Working Group to the Public Health Commission on the National Immunisation Strategy*, Wellington, 1993.

<sup>119</sup> CDCAC minutes, 7 December 1993, Ministry of Health Archives, Wellington. .

<sup>120</sup> Department of Health, *Immunisation Handbook*, Wellington, 1993. This was the first of a series of handbooks designed to bring together information on the New Zealand immunisation schedule for health professionals.

as the previous chapter discussed, Milne's focus had shifted by the mid-1990s from childhood immunisation to the promotion of screening for hepatitis B carriers.<sup>121</sup>

In the 1995 *National Immunisation Strategy*, Shipley affirmed her commitment to improving immunisation coverage through a range of measures, including enhanced immunisation surveillance and the introduction of immunisation checks in schools and preschools.<sup>122</sup> In 1996, she adopted the PHC's immunisation targets.<sup>123</sup> Nevertheless, she provided little in the way of resources or advocacy to implement the new immunisation initiatives. While adjustments were made to simplify the immunisation schedule, and local immunisation coordinators were appointed, the proposed surveillance system did not materialise, and no funding was made available for the introduction of immunisation certificates for children entering schools and early childhood centres.

During the mid-1990s, few improvements were recorded in coverage rates. A coverage survey commissioned by the Northern Regional Health Authority in 1996 showed that there had been 'modest' gains in Auckland and Northland since the national survey in 1992, but that these improvements were barely discernible among Maori children.<sup>124</sup> An estimated 63 per cent of children in the northern region were fully immunised by the age of two years, while immunisation coverage among two year old Maori and Pacific children was estimated at 45 per cent and 53 per cent respectively.<sup>125</sup> Furthermore, only

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<sup>121</sup> Milne did, however, maintain a strong interest in immunisation projects in the Pacific and in other high prevalence areas such as Vietnam. V. Edwards, *Battling the Big B: Hepatitis B in New Zealand*, pp.79-86; pp.166-74.

<sup>122</sup> Ministry of Health, *National Immunisation Strategy 1995*, Wellington, 1995.

<sup>123</sup> Ministry of Health, *Immunisation 2000*, Wellington, 1996. In 1994 the PHC recommended a target of 85 per cent immunisation coverage among two year old children by the year 1997, and 95 percent or more by the year 2000.

<sup>124</sup> As noted in Chapter Seven, four Regional Health Authorities were established in 1993 as part of the health reforms. At the same time, the 14 area health boards established under Helen Clark in 1989 were reconfigured into 23 Crown Health Enterprises.

<sup>125</sup> W. Rainger, N. Solomon, N. Jones, J. Jarman, N. Turner, D. Lennon, J. Stewart, 'Immunisation coverage and risk factors for immunisation failure in Auckland and Northland', *New Zealand Public Health Report*, 5, 7, July 1998, pp.49-51.

63 per cent of two year old Maori children compared with 85 per cent of children of ‘other ethnicities’ were fully immunised against hepatitis B.<sup>126</sup>

In 1997, the health sector entered another period of upheaval. The National New Zealand First Coalition Government (1997–1998), the first to be formed after the introduction of a new electoral system, ‘re-reformed’ the structure of the public health system. As Gauld observed, the “‘re-reforms’ era’ was marked by further ‘uncertainty and disruption’ as the Coalition Government negotiated new directions in health policy from differing ideological standpoints.<sup>127</sup> During this period, some public health initiatives received considerable funding from the Coalition Government, notably the hepatitis B screening programme, while other preventive health programmes, including immunisation, appeared to languish. In 1999, Ministry of Health statistics suggested that immunisation coverage for individual vaccines, including hepatitis B, was generally lower than had been reported in 1996.<sup>128</sup>

During the 1990s, the continual changes to the public health system, the emphasis on cost containment, and the lack of political advocacy for childhood immunisation hindered attempts to improve immunisation coverage. Levels remained low, particularly among Maori and Pacific children, and as a consequence, a high proportion of at-risk children remained susceptible to hepatitis B and other vaccine-preventable diseases.

### **International comparisons**

The failure of the New Zealand immunisation programme to protect high risk children from hepatitis B virus infection during the 1990s was even more striking when compared with international efforts to control the disease. Taiwan and Alaska, in particular, reported high coverage levels for the hepatitis B vaccine during this period.

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<sup>126</sup> *ibid.* These results were consistent with the evaluation study of hepatitis B immunisation rates among Northland infants conducted in the early 1990s, which found that 63 per cent of Maori and 80 per cent of European infants completed the hepatitis B schedule. C. Salmond, D. Bandaranayake, ‘Progress of the neonatal hepatitis B immunisation programme in Northland’, p.233.

<sup>127</sup> R. Gauld, *Revolving Doors: New Zealand’s Health Reforms – the Continuing Saga*, p.170.

<sup>128</sup> Ministry of Health, *Progress on Health Outcomes Targets 1999*, Wellington, 1999.

In the 1970s hepatitis B was highly endemic in Taiwan, where over 15 per cent of the adult population were chronic carriers of the virus.<sup>129</sup> In 1984 the government launched a nationwide hepatitis B immunisation programme for the babies of carrier mothers. This programme was expanded to all infants in 1986 and to all preschool children in 1987. Despite public concerns over the safety of the plasma-derived vaccine, immunisation coverage during the first five years of the programme averaged 88 per cent.<sup>130</sup> A decade later, in 1996, Taiwan reported that over 90 per cent of preschool children had been fully immunised against hepatitis B. As a result, childhood hepatitis B carrier rates fell dramatically, from 9.8 per cent in 1984, to 1.3 per cent in 1994.<sup>131</sup>

In some respects, the introduction of the Taiwan hepatitis B control programme mirrored the New Zealand experience. To contain the cost of the vaccine, the hepatitis B immunisation programme focused initially on the babies of carrier mothers and increased incrementally to cover infants and preschool children.<sup>132</sup> In 1988 primary school children, and in 1989, high school children were added to the immunisation schedule. Taiwan continued to expand its hepatitis B programme, however; college students and adults susceptible to the virus were added to the immunisation schedule in the early 1990s. Government responses to the disease also differed. Whereas in New Zealand, the Health Department was reluctant to introduce a comprehensive hepatitis B immunisation programme, in Taiwan in the early 1980s the government funded an extensive programme of public education and research, and in the mid-1980s, provided sufficient resources for the implementation and evaluation of the national immunisation strategy.<sup>133</sup>

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<sup>129</sup> Epidemiological studies in the 1970s showed that the hepatitis B carrier rate in the Taiwan population was between 15 and 20 per cent. See for example, I. D. Gust, 'Immunisation against hepatitis B in Taiwan', *Gut*, 38, Supplement 2, 1996, p.67.

<sup>130</sup> *ibid.*, pp.67-8. C. Chan, S. Lee, K. Lo, 'Legend of hepatitis B vaccination: The Taiwan experience', *Journal of Gastroenterology and Hepatology*, 19, 2004, pp.121-6. According to the authors, hostility towards the blood-based vaccine was initially strong, as parents feared it might contribute to the spread of AIDS or other blood borne diseases. *ibid.*, p.122.

<sup>131</sup> H. Chen, M. Chang, Y. Ni, H. Hsu, P. Lee, C. Lee, D. Chen, 'Ten years of mass hepatitis B immunisation in Taiwan', *JAMA*, 276, 11, 18 September 1996, pp.906-8.

<sup>132</sup> I. D. Gust, 'Immunisation against hepatitis B in Taiwan', pp.67-8.

<sup>133</sup> *ibid.* From 1982 to 1998, Taiwan spent US \$100 million on its hepatitis B control programme. K. Huang, S. Lin, 'Nationwide vaccination: A success story in Taiwan', *Vaccine*, 18, 2000, pp.35-8.

In the early 1980s, Alaskan Natives also had high rates of hepatitis B prevalence.<sup>134</sup> In 1983, a hepatitis B prevention programme for indigenous Alaskans was introduced in a cooperative agreement between the Alaskan Native Medical Service, the Alaska Health Department and Alaska Native health organisations.<sup>135</sup> Preliminary results of the immunisation programme and the associated hepatitis B screening programme, published in 1987 were encouraging.<sup>136</sup> As discussed in the previous chapter, the apparent success of the Alaskan programme influenced the aspirations of Alexander Milne and Chris Moyes to introduce a hepatitis B screening programme in New Zealand. By 1993, 93 per cent of Native Alaskan children less than ten years of age had been immunised against hepatitis B. Among the children surveyed, none were hepatitis B carriers, leading to the conclusion that the spread of chronic hepatitis B virus infection had been eliminated among Native Alaskan children born since the introduction of the immunisation programme.<sup>137</sup>

In the US, certain ethnic groups were found to have high rates of childhood hepatitis B virus infection. These groups included Alaskan Natives, Pacific peoples and the babies of first-generation immigrants from parts of the world where hepatitis B was endemic, particularly Asia. In 1991, universal infant hepatitis B immunisation was adopted as part of a comprehensive strategy to eliminate hepatitis B.<sup>138</sup> Four years later, in 1995, the US Advisory Committee on Immunisation Practices recommended the immunisation of all 11 and 12 year old children against hepatitis B.<sup>139</sup> In 1997, the Centers for Disease

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<sup>134</sup> Prevalence rates among Alaskan Natives varied from region to region, from 0.5 per cent to 8.2 per cent. R. Harpaz, B. J. McMahon, H. S. Margolis, C. N. Shapiro, D. Havron, G. Carpenter, L. Bulkow, R. B. Wainwright, 'Elimination of new chronic hepatitis B virus infections: Results of the Alaska immunization program', *Journal of Infectious Diseases*, 181, February 2000, p.414.

<sup>135</sup> *ibid.*, p.413.

<sup>136</sup> B. J. McMahon, W. L. Heyward, D. Ritter, R. B. Wainwright, E. R. Rhoades, E. Tower, A. P. Lanier, C. Helminiak, 'A comprehensive programme to reduce the incidence of hepatitis B virus infection and its sequelae in Alaskan natives', pp.1134-6.

<sup>137</sup> R. Harpaz, B. J. McMahon, H. S. Margolis, C. N. Shapiro, D. Havron, G. Carpenter, L. Bulkow, R. B. Wainwright, 'Elimination of new chronic hepatitis B virus infections: Results of the Alaska immunization program', pp.413-8.

<sup>138</sup> Recommendations of the Advisory Committee on Immunization Practices (ACIP): 'Hepatitis B Virus: A comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination', *MMWR*, 40, RR-13, 22 November 1991, pp.1-19.

<sup>139</sup> CDC, 'Update: Recommendations to prevent hepatitis B transmission – United States', 44, 1995, *MMWR*, pp.574-5.

Control (CDC) reported that by three years of age, more than 84 per cent of US children were fully immunised against hepatitis B. Furthermore, by 2000, coverage among adolescents had increased from near zero to 67 per cent.<sup>140</sup>

Australia introduced hepatitis B immunisation in a staged programme that initially targeted the indigenous population, which was known to have a higher prevalence of the disease. The ‘at risk’ programme for infants began in 1987, and in 1990 free infant hepatitis B immunisation became available in the Northern Territory.<sup>141</sup> In the mid-1990s, Australia introduced a number of immunisation initiatives that increased overall immunisation coverage dramatically. These initiatives included the introduction of a recall and reminder system based on a national immunisation register, improved immunisation surveillance, and financial incentives for caregivers. By 1998, overall immunisation coverage among two year old children had increased from 64 to 85 per cent.<sup>142</sup> When universal infant hepatitis B immunisation was included on the routine immunisation schedule in mid-2000, therefore, vaccine uptake was substantial. Seven years later, almost 95 per cent of Australian infants aged 12 to 15 months were fully immunised against hepatitis B.<sup>143</sup>

During the 1990s, New Zealand’s hepatitis B immunisation programme was wide-ranging in intent. However, the actual delivery of hepatitis B vaccine in New Zealand fell well behind that achieved in other countries where hepatitis B posed a public health problem, whether vaccine was delivered through ethnically-targeted programmes or

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<sup>140</sup> CDC, ‘Hepatitis B vaccination – United States, 1982-2002’, *MMWR*, 51, 25, 28 June 2002, pp.549-52.

<sup>141</sup> A. Williams, ‘Reduction in the hepatitis B related burden of disease – measuring the success of universal immunisation programmes’, *Communicable Diseases Intelligence*, 26, 2002, pp.458–60, cited in J. Wallace, S. McNally, J. Richmond, *National Hepatitis B Needs Assessment*, Australian Research Centre in Sex, Health and Society, Melbourne, 2008, p.16, online, available at: [http://www.ashm.org.au/images/publications/guidelines/07hepbneedsassess\\_000.pdf](http://www.ashm.org.au/images/publications/guidelines/07hepbneedsassess_000.pdf). Of the seven Australian states, the Northern Territory has the highest proportion of indigenous people in its population (22 per cent compared with a nationwide average of 2.4 per cent in 1991). Australian Bureau of Statistics, ‘3105.0.65.001 Australian Historical Population Statistics, 2008’, online, available at: <http://www.abs.gov.au/AUSSTATS/abs@.nsf/0/C159FA62A2E98D2FCA2568A9001393E4?OpenDocument> (22 May 2010).

<sup>142</sup> N. Turner, M. Baker, J. Carr, O. Mansoor, ‘Improving immunisation coverage: what needs to be done?’, p.12.

<sup>143</sup> J. Wallace, S. McNally, and J. Richmond, *National Hepatitis B Needs Assessment*, p.16.

routine immunisation schedules. New Zealand health officials were reluctant to consider ethnically-targeted immunisation, which they regarded as potentially stigmatising and discriminatory, yet successive governments were unwilling to provide adequate resources to improve immunisation coverage, particularly among 'high risk' children.

### **Protecting the babies of carrier mothers**

Chapter Four drew attention to the importance of preventing infection in the babies of hepatitis B carrier mothers. Without protective immunisation, these babies were at high risk of becoming hepatitis B carriers.<sup>144</sup> When the hepatitis B vaccine was first introduced in New Zealand, the babies of carrier mothers took priority for policy attention.

The New Zealand Health Department began providing state-funded immunisation for the babies of highly infectious (hepatitis B e antigen positive) carrier mothers in September 1985.<sup>145</sup> Following the recommendations of the US Advisory Committee on Immunization Practices, these babies received hepatitis B immunoglobulin and hepatitis B vaccine at birth, with two further doses of vaccine at six weeks and five months of age. A blood test at twelve months of age was also recommended to identify those babies who required further immunisation, and to provide some measure of the efficacy of the programme.<sup>146</sup> Initially, about 300 babies per year were eligible for free immunisation. This number increased to approximately 1650 each year following the expansion of the programme in early 1987 to include the babies of all carrier mothers, regardless of their hepatitis B e antigen status.<sup>147</sup>

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<sup>144</sup> G. L. Mandell, J. E. Bennett and R. Dolin, *Principles and Practice of Infectious Diseases*, p.1442.

<sup>145</sup> Hepatitis B e antigen positive mothers posed a very high risk of transmitting the virus to their babies (up to 90 per cent), while the risk posed by carrier mothers without the e antigen was much less.

<sup>146</sup> Recommendations of the Immunization Practices Advisory Committee (ACIP), 'Postexposure prophylaxis of hepatitis B', MMWR, 1984, 33, pp.285-90.

<sup>147</sup> Department of Health, Circular Letter (Hosp) No. 1985/112, 25 September 1985, 'Hepatitis B Immunisation of At Risk Neonates', ZABV A1073 96c, ANZA; Department of Health, Circular Letter to Medical Practitioners, HP 1/87, January 1987, 'Hepatitis B – Department of Health Immunisation Programme', ZABV A1073/886b/1, ANZA.



While the immunisation policy for the babies of carrier mothers appeared relatively straightforward on paper, implementing the programme in practice was far from simple. During the antenatal period, pregnant women were screened routinely to detect those who were hepatitis B carriers. However, not all women presented for antenatal care, so that some women arrived at maternity hospitals to give birth with no record of their hepatitis B status.<sup>148</sup> While the initial immunisation was given by hospital staff, subsequent doses of vaccine were given by family doctors. In some cases, it proved impossible to maintain contact with mothers who moved across hospital board boundaries, and to ensure that their babies received complete courses of hepatitis B vaccine.

In 1989 concerns were expressed within the Health Department as to the proportion of babies of carrier mothers who received their first and subsequent immunisations.<sup>149</sup> A survey of 19 area health boards and health development units revealed problems implementing the programme, which primarily involved Maori and Pacific mothers and babies.<sup>150</sup> While some areas such as Central and South Auckland, Takapuna, Tairāwhiti, Napier, Wanganui, and West Coast, reported 95 to 100 per cent success with the initial immunisation of these babies, other areas with substantial Maori populations, such as Waikato and Rotorua, either did not respond to the survey or could not estimate their follow up rates. Further, only Central and South Auckland appeared to follow a systematic process for notifying family doctors of the need to immunise the babies of carrier mothers at the 'six-week' postnatal visit. Estimates for the uptake of the second and subsequent dose of vaccine were provided by five districts, four of which indicated that rates fell off rapidly after each dose.<sup>151</sup>

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<sup>148</sup> *ibid.* While provisions were made for situations such as these, the observation was made that babies of mothers screened 'late' were more likely to be lost to the 'system', and to miss out on subsequent immunisations in the community.

<sup>149</sup> Johns to Associate Minister of Health, 'Hepatitis B Policy Review', 19 December 1990, ABQU 632 W4452/698 131/171/1 70059, ANZW.

<sup>150</sup> Health Services Research and Development Unit, 'Vaccination Programme for Carrier Mothers: Process Evaluation of the Hepatitis B Immunisation Programme for Children Born to Carrier Mothers (1989/90)', July 1989, ABQU 632 W4452/1951 372/21/6 73274. Even though the data provided by the area health boards was incomplete, it was clear that carrier rates were 'markedly higher for Maori and Polynesian mothers than for European mothers'.

<sup>151</sup> *ibid.*

While the findings of the 1989 survey provided a degree of reassurance that the initial immunisation was given in most cases, no action was taken to improve follow up procedures. The 1990 review of hepatitis B policy noted that the identification and follow up of the babies of carrier mothers needed further evaluation. Nevertheless, the issue remained dormant until late 1991, when Alexander Milne wrote to Ian Millar, acting Director-General of Health, to question whether the babies of carrier mothers were receiving adequate care. Milne, who had established a hepatitis B carrier register in Whakatane, lobbied Millar for his support for a system of ‘central surveillance’ to ensure that these babies were identified and immunised.<sup>152</sup> In response, Millar allocated funding for a formal evaluation of the programme.<sup>153</sup> While this project did not eventuate, in mid-1992 the NZCDC produced a report for the Health Department in which it outlined a variety of evaluation strategies.<sup>154</sup>

The Department considered the NZCDC report, but did not act on it. In 1992, as noted earlier in this chapter, the health sector was in a state of ‘organisational flux’, with radical reforms underway to reduce health expenditure. The options proposed by the NZCDC were relatively inexpensive, but it was an inopportune time to seek additional funding for hepatitis B prevention, which was no longer seen as a pressing public health priority. In 1993, Dr Nicholas Wilson, a community medicine specialist and co-author of the NZCDC report, revisited the issue in his Master of Public Health thesis on the epidemiology and control of hepatitis B in New Zealand. Wilson described the lack of formal evaluation of the programme for the babies of carrier mothers as a ‘major deficiency’ of New Zealand’s hepatitis B strategy; however, there was no response to his pointed critique of official policy.<sup>155</sup>

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<sup>152</sup> Milne to DGH, 24 September 1991, ABQU 632 W4452/699 131/171/1 76900, ANZW.

<sup>153</sup> Johnston to Tobias, Follow up of babies born to mothers who are infectious carriers of hepatitis B, 11 October 1991, ABQU 632 W4452/699 131/171/1 76900, ANZW.

<sup>154</sup> NZCDC, Internal Memorandum, Wilson and Baker to Talbot and Patel, ‘Report for Public Health Services, Department of Health: Evaluation Strategies for the Prevention of Hepatitis B in Infants Born to Carrier Mothers’, 22 June 1992, ABQU 632 W4452/699 131/171/1, ANZW.

<sup>155</sup> N. Wilson, ‘The Epidemiology and Control of Hepatitis B in New Zealand’, Master of Public Health thesis, University of Otago, 1993, p.4.

During the 1990s, and after 2000, the programme targeting the babies of carrier mothers remained an integral part of New Zealand's hepatitis B prevention programme. Local reviews in the Auckland and Wellington regions in 2001 found that the immunisation rates among these babies 'fell short of 100%', however, no nationwide information on the programme was collected until early 2005, during the first national immunisation coverage survey since 1992.<sup>156</sup> Of the babies of 31 carrier mothers interviewed, 63 received hepatitis B immunoglobulin 'on time', 23 per cent received it later than recommended, and 13 per cent had no record of ever receiving it.<sup>157</sup> These results suggested that, despite the importance of achieving full immunisation coverage among this high risk group of infants, there were still difficulties in implementing the policy.

New Zealand was not the only country to experience problems with this aspect of hepatitis B prevention. In Taiwan, an evaluation of the first six years of the national hepatitis B programme showed that that 22 per cent of pregnant women missed out on routine hepatitis B screening, and that only 70 per cent of the babies of carrier mothers received hepatitis B immunoglobulin after birth.<sup>158</sup> Similarly, in reports published in 1990 and 1996, the CDC emphasised the difficulties of identifying and following up the babies of carrier mothers, and in 2005, the Advisory Committee on Immunisation Practices admitted that this facet of the US hepatitis B programme 'remained a challenge'.<sup>159</sup>

The implementation of the policy to protect the babies of carrier mothers was more complex than anticipated; nevertheless, problems detected in 1989 were put to one side, and no attempt was made to evaluate the programme during the 1990s. Other priorities

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<sup>156</sup> Public Health Protection, Auckland DHB, 'Improving hepatitis B immunisation coverage in high-risk infants in Auckland', 2001; Regional Public Health, Hutt Valley DHB, 'Review of neonatal prophylaxis in Wellington', 2001, cited in Ministry of Health, *The National Immunization Coverage Survey 2005*, Wellington, 2007, p.42.

<sup>157</sup> *ibid.*, p.28. For the purposes of the 2005 survey, 'on time' was considered to be within 48 hours of birth. Although it was recommended that immunoglobulin and vaccine were given to the babies of carrier mothers as soon as possible after birth, they could be given for up to seven days after birth.

<sup>158</sup> I. D. Gust, 'Immunisation against hepatitis B in Taiwan', p.68.

<sup>159</sup> Advisory Committee on Immunization Practices (ACIP), 'A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States, part 1: Immunization of infants, children and adolescents', *MMWR*, 54, RR-16, 23 December 2005, pp.1-23.

intervened, and the failings of this small, but significant, component of the hepatitis B control strategy were largely ignored by health officials and policy makers.

### **Contemporary issues**

A change of government at the end of 1999 brought a renewed pledge to improve immunisation coverage among New Zealand children. Progress was made towards introducing immunisation initiatives for 'hard to reach' children between 1999 and 2005, yet ethnic disparities in coverage persisted.

Following the general election in late November 1999, a Labour-led coalition government was formed. The new government, which had already flagged its plans for a restructure of the public health system, expressed a strong commitment to preventive health strategies and the reduction of social and ethnic disparities in health.<sup>160</sup>

Immunisation was among the first public health projects to come to the attention of Annette King, the Health Minister and a former dental nurse. King endorsed the principal recommendation of the recently released National Health Committee advice on strategies to improve the immunisation coverage of 'hard to reach' children: that 90 per cent coverage of two year old children 'in all population groups' by July 2003 be made a 'performance expectation within the accountability arrangements' between the Minister of Health and the public health services.<sup>161</sup>

High level advocacy for childhood immunisation was long overdue. In early 2000, the Director of the Auckland-based Immunisation Advisory Centre, Dr Nikki Turner, and other public health experts, pointed to the first case of diphtheria in 19 years and the

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<sup>160</sup> See for example, R. Gauld, *Revolving Doors: New Zealand's Health Reforms – The Continuing Saga*, p.182; R. Beaglehole and R. Bonita, *Public Health at the Crossroads*, p.218; L. Bryder, 'Health Citizenship and "Closing the Gaps": Maori and Health Policy', pp.51-61.

<sup>161</sup> NHC, Media Release, 'Action on immunisation of New Zealand's 'hard to reach' children', 1 December 1999, online, available at: <http://www.nhc.health.govt.nz/moh.nsf/indexcm/nhc-news-action-on-immunisation-1dec99> (22 November 2009). The National Health Committee (NHC) was established in March 1992 as the National Advisory Committee on Core Health Services. In January 1996 the committee's brief was extended to include advice on public health and public health matters, and in 1998 it was renamed the National Advisory Committee on Health and Disability, more commonly known as the National Health Committee. The National Health Committee, 'About Us', online, nd, available at: <http://www.nhc.health.govt.nz/moh.nsf/indexcm/nhc-aboutus-role> (4 May 2009).

levelling off of the decline in notifications of acute hepatitis B virus infection as evidence of inadequate immunisation coverage. As Maori and Pacific children had only about 60 per cent coverage against hepatitis B, they estimated it was 'likely that only about half the potential gains [of the hepatitis B immunisation programme] were being achieved'.<sup>162</sup>

In 2001, King introduced an *Integrated Approach to Infectious Disease: Priorities for Action 2002-2006*, which defined public health strategies for the management of infectious diseases. Vaccine-preventable diseases and the low levels of immunisation coverage in children received the highest priority for action: 'the consensus within the infectious diseases sector ... is that improving vaccination rates in children is the top priority in infectious disease control'. Somewhat optimistically, given the past difficulties in improving coverage rates, the immunisation target was raised to 95 per cent of children fully immunised at the age of two years by 2005.<sup>163</sup>

Despite the apparent urgency to address immunisation issues, however, it was more than two years before significant steps were taken to implement the strategies outlined in the 2001 policy document. In December 2003, in the foreword to *Immunisation New Zealand: Strategic Directions 2003 –2006*, Dr Karen Poutasi, Director-General of Health, announced the Government's intention to establish a computerised national immunisation register and to improve access to immunisation services in primary care and outreach clinics, among other immunisation initiatives. In reference to the persistently low vaccine uptake among Maori and Pacific children, Poutasi acknowledged that 'the burden of vaccine-preventable disease ... fell heavily on Maori and Pacific Island populations' and reiterated that the improvement of immunisation coverage among these groups was 'a priority'.<sup>164</sup>

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<sup>162</sup> N. Turner, M. Baker, J. Carr, O. Mansoor, 'Improving immunisation coverage: what needs to be done?', pp.11-4.

<sup>163</sup> Ministry of Health, *Integrated Approach to Infectious Disease: Priorities for Action 2002-2006*, Wellington, 2001, p.10. In addition, as part of the strategy to reduce the spread of blood borne viruses, hepatitis B immunisation was recommended, although not publicly funded, for high risk adults, such as health care workers, prison inmates and injecting drug users.

<sup>164</sup> Ministry of Health, *Immunisation in New Zealand: Strategic Directions 2003-2006*, Wellington, 2003.

While improvements in coverage were clearly needed, the development of a vaccine to combat the ongoing epidemic of group B meningococcal disease, which began in the early 1990s, arguably provided the final stimulus for the Labour Government to proceed with the development of a national immunisation register. Young Maori and Pacific children in South Auckland bore the brunt of the epidemic; however, children and adults of all ethnicities were affected.<sup>165</sup> The introduction of the MeNZ B vaccine, ‘tailor-made’ for the New Zealand epidemic strain, required a nationwide computerised immunisation register to monitor vaccine safety and accurately record coverage data.<sup>166</sup>

The national immunisation coverage survey, conducted in early 2005, provided the first nationwide coverage data since 1992. While the 2005 survey showed an improvement in coverage since the early 1990s, it highlighted persistent ethnic disparities: only 69 per cent of Maori children were fully immunised at the age of two years compared with 80 per cent of European children. In contrast to previous studies, Pacific children had the highest coverage levels of all ethnic groups; nevertheless, this finding was not consistent with the findings of the hepatitis B screening programme or with data collected on the national immunisation register after it went live nationwide in late 2005.<sup>167</sup>

In his 2006 Master of Public Health thesis on hepatitis B control in New Zealand, Dr Simon Thornley, a public health physician, concluded that the screening programme had shown that there was ‘considerable room for improvement in Pacific immunisation coverage in infancy’. An estimated 42 per cent of child contacts of Pacific carriers aged

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<sup>165</sup> See for example, D. Martin, R. McDowell, *The Epidemiology of Meningococcal Disease in New Zealand in 2003: Report prepared for the Ministry of Health by the Institute of Environmental Science and Research Ltd (ESR)*, Wellington, 2004, online, nd, available at: [http://www.moh.govt.nz/moh.nsf/0/C088F437895D6DC8CC256ED1000B2539/\\$File/epidemiologyofmeningococcaldisease2003.pdf](http://www.moh.govt.nz/moh.nsf/0/C088F437895D6DC8CC256ED1000B2539/$File/epidemiologyofmeningococcaldisease2003.pdf) (24 May 2010).

<sup>166</sup> K. Sexton, D. Lennon, P. Oster, S. Crengle, D. Martin, K. Mulholland, T. Percival, S. Reid, J. Stewart, J. O’Halohan, ‘The New Zealand meningococcal vaccine strategy: A tailor-made vaccine to combat a devastating epidemic’, *NZMJ*, 117, 1200, 20 August 2004, online, available at: <http://www.nzma.org.nz.ezproxy.auckland.ac.nz/journal/117-1200/1015/content.pdf> (20 May 2010).

<sup>167</sup> Ministry of Health, *The National Immunisation Coverage Survey 2005*, 2007. The national immunisation register, which started operating in July 2004, was rolled out throughout New Zealand starting with the Auckland region in April 2005 and finishing in Nelson/Marlborough in December 2005, online, nd, available at: [http://www.moh.govt.nz/moh.nsf/wpg\\_index/About-NIR+FAQs#nine](http://www.moh.govt.nz/moh.nsf/wpg_index/About-NIR+FAQs#nine) (4 May 2009).

0–14 years were found to be non-immune to hepatitis B, and 2 per cent were chronically infected with the virus.<sup>168</sup> Thornley argued that the high numbers of susceptible children identified by the screening programme, and the previous estimates of immunisation coverage among Maori and Pacific children, called for a policy response.<sup>169</sup>

## **Conclusion**

In early 1990, with the introduction of universal childhood hepatitis B immunisation, and the provision of short-term strategies targeting children in ‘high risk’ communities, prospects for reducing the prevalence of hepatitis B among New Zealand children appeared positive. Nevertheless, immunisation coverage was poor, especially among Maori and Pacific children, and public health officials were aware that broader immunisation initiatives would be required to ensure adequate uptake of the vaccine. In spite of urging the Health Minister, Helen Clark, to prioritise childhood immunisation, she chose not to include it among the ‘health goals’ for the 1990s, a decision that had important implications for resource allocation.

The extensive involvement of a private vaccine venture in the ‘high risk’ hepatitis B initiatives in early 1990 led to widespread difficulties when it collapsed partway through its immunisation contracts. In the confusion that ensued, Alexander Milne emerged as the champion of the ‘right’ of high risk groups to be screened before hepatitis B immunisation, and in late 1990, as the favoured provider for further ‘high risk’ hepatitis B immunisation projects. The commotion caused by private ventures and pre-immunisation screening in the early 1990s overshadowed the most important issue – how best to deliver hepatitis B vaccine to ‘hard to reach’ children who were often at the highest risk of infection? In theory, the problem of low hepatitis B immunisation rates among high risk children was expected to end as the infant immunisation programme steadily reduced the susceptible childhood population. In reality, this assumption was

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<sup>168</sup> S. Thornley, ‘Hepatitis B: Mathematical Modelling, Transmission Dynamics and Infection Control in New Zealand’, Master of Public Health thesis, University of Auckland, 2006, p.75.

<sup>169</sup> *ibid.*, p.79.

flawed by the low levels of immunisation coverage which persisted in Maori and Pacific communities.

Throughout the 1990s, repeated restructuring of the public health system undermined efforts to improve immunisation coverage and to evaluate the effectiveness of the hepatitis B control programme. While impressive immunisation targets were set, few resources were made available for immunisation initiatives, and hepatitis B prevention in New Zealand compared poorly with international efforts to control the disease.

Innovative strategies implemented in the early 2000s improved coverage rates; however, marked ethnic discrepancies were still evident in 2005, leading at least one observer to revisit proposals for targeted hepatitis B immunisation policies.



## CHAPTER NINE

### THE HEPATITIS B INFECTED HEALTH CARE WORKER: POLICY RESPONSES 1990–2005

In 1991, the risk to patients from health care workers infected with blood borne viruses was brought to widespread public attention by the Centers for Disease Control (CDC), which reported that a US dentist had infected five of his patients with the human immunodeficiency virus (HIV).<sup>1</sup> The intense media and community interest in this unprecedented case prompted health authorities in the US and the UK to re-examine their policies for infected health care workers. The hepatitis B virus, which is much more readily transmitted than HIV, was known to have been spread from health care workers to at least 350 patients since the early 1970s.<sup>2</sup> Nevertheless, prior to 1990 the risk of acquiring hepatitis B during routine patient procedures had attracted little public concern. Fear of Acquired Immune Deficiency Syndrome (AIDS), rather than hepatitis B, provided the initial stimulus to reconsider the problem of infected health care workers.

During the early 1990s, distinctly different policies for the management of HIV and hepatitis B infected health care workers were developed in different health jurisdictions. The lack of international consensus on this issue reflected the complex medical, ethical and legal factors involved. Opinions varied on the acceptable level of risk for patients undergoing invasive procedures, and the rights and responsibilities of infected health care workers. Professional careers were at stake, and in most countries, calls for the mandatory testing of health care workers for HIV and hepatitis B virus were strongly resisted by professional organisations. The potential for acquiring HIV was uppermost in

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<sup>1</sup> CDC, 'Possible transmission of human immunodeficiency virus to a patient during an invasive dental procedure', MMWR, 39, 27 July 1990, pp.489-93; CDC, 'Epidemiologic Notes and Update: transmission of HIV infection during an invasive dental procedure – Florida', MMWR, 40, 18 January 1991, pp. 21-7, p.33; CDC, 'Epidemiologic Notes and Update: transmission of HIV infection during invasive dental procedures – Florida', MMWR, 40, 14 June 1991, pp.377-81.

<sup>2</sup> CDC, 'Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures', MMWR, 40, RR-08, 12 July 1991, pp.1-9.

the public mind, and in 1996, the first report of hepatitis C virus transmission from clinician to patient raised the prospect of transmission of other, as yet unidentified, blood borne pathogens.<sup>3</sup> Nonetheless, the hepatitis B virus remained an important focus for health policy makers because of its high transmissibility and the availability of an effective vaccine.

This chapter will discuss the development of policy for hepatitis B infected health care workers in New Zealand from 1990 to 2005. The US and the UK policies will be examined in some detail; they represented polar opposites in the possible reactions to the problem of infected health care workers, and therefore provide a useful context in which to consider New Zealand's policy responses. As background to the developments of the 1990s, the chapter will begin by discussing the tolerant attitudes that persisted in the 1980s in US, the UK, and New Zealand towards hepatitis B carriers in the health workforce. It will then consider New Zealand's reluctance to adopt either the precautionary policies introduced in the UK in the 1990s, or the more *laissez-faire* policies followed in the US. It will conclude by discussing policy developments after 2000, and the ongoing debate over the management of hepatitis B infected health care workers.

### **Protecting health care workers at risk**

Prior to 1990, policies to prevent the transmission of hepatitis B and HIV in the health care setting were primarily focused on the occupational risk of blood borne viruses. In New Zealand, as in the UK and US, the intention of policymakers was to protect health care workers at risk, and, as a corollary, to defend the rights of HIV and hepatitis B infected workers to continued employment.

Chapter Three discussed the issues that arose in the 1970s when the introduction of tests to detect hepatitis B revealed that a surprising number of health care workers had been

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<sup>3</sup> J. L. Esteban, J. Gomez, M. Martell, B. Cabot, J. Quer, J. Camps, A. Gonzalez, T. Otero, A. Moya, R. Esteban, J. Garcia, 'Transmission of hepatitis C by an infected surgeon', *NEJM*, 334, 9, 29 February 1996, pp.555-60.

infected by the virus. Hepatitis B can be transmitted by a chronic carrier or an asymptomatic person who is incubating the disease, so that infected health care workers were seen to pose a potential risk to their patients. However, in both the UK and the US, senior members of the medical profession argued that these risks were rare, and that practice restrictions need not apply unless cross-transmission could be proven.

During the 1980s, the AIDS epidemic increased professional concerns over the hazards of blood borne viruses in the health workplace. While hepatitis B remained a recognised risk for health care workers, fears of acquiring HIV provided the incentive for new approaches to infection control. Described by the CDC as 'universal precautions', health authorities in the US and the UK recommended that all patients should be treated as potentially infectious, and that staff exposure to blood and body fluids should be reduced by the routine use of gowns, gloves, masks, and protective eyewear. During the 1980s the concept of universal precautions was adopted widely in policies aimed at protecting health care workers from occupational exposure to HIV and the hepatitis B virus.<sup>4</sup>

In 1989, at the instigation of the AIDS Advisory Committee, the New Zealand Health Department developed guidelines to prevent HIV and hepatitis B transmission in the health care setting.<sup>5</sup> The departmental recommendations were consistent with those published by the US and the UK health authorities.<sup>6</sup> They emphasised the high occupational risk of acquiring blood borne infections from patients and contaminated

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<sup>4</sup> CDC, 'Recommendations for prevention of HIV in health-care settings', MMWR, 36, Supplement 2S, 21 August 1987.

<sup>5</sup> Department of Health, *Hepatitis B and HIV Transmission: Prevention in Health Care Settings*, Wellington, 1989. The AIDS Advisory Committee was set up in July 1985 to 'provide expert technical advice to the Minister and Health Department on the management of AIDS in New Zealand'. AJHR, 1986, E.10, p.21.

<sup>6</sup> CDC, 'Perspectives in disease prevention and health promotion update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings', MMWR, 37, 24 June 1988, pp.377-88; Hospital Infection Society, 'Acquired immune deficiency syndrome: recommendations', *Journal of Hospital Infection*, 6, Supplement C, 1985, pp.67-80, cited in Hospital Infection Society, 'Acquired immune deficiency syndrome: recommendations of a Working Party of the Hospital Infection Society', *Journal of Hospital Infection*, 15, 1990, pp.7-34; UK Department of Health, Recommendations of the Expert Advisory Group on AIDS, *AIDS: HIV Infected Health-care Workers*, London, 1988.

equipment, and the need for ‘universal blood precautions’ to reduce the risks of occupational exposure.<sup>7</sup>

Like the US and the UK recommendations, the New Zealand guidelines paid little attention to the risks to patients. Only five lines were devoted to the management of the infected health care worker, an indication of the low priority that was given to the issue. On the grounds that ‘the [hepatitis B virus] has not been widely transmitted from infected staff to patients and for HIV the risk of transmitting the virus is considered to be extremely small’, the Department defended the rights of infected health care workers to privacy and protection from discrimination. Screening health care workers for HIV and hepatitis B was discouraged as ‘inappropriate’.<sup>8</sup> Whereas in the UK, infected workers who performed invasive patient procedures were advised to seek counselling and occupational advice about ‘a possible change in duties’, in New Zealand, they were directed to ‘discuss the matter in confidence with an appropriate specialist’.<sup>9</sup> The guidelines reflected the wider consensus: protecting health care workers from viral infection was of primary importance, and those workers who became hepatitis B or HIV positive had a right to unrestricted practice given the extremely small risk involved.<sup>10</sup>

In her PhD thesis on hepatitis B policy in the UK, Jennifer Stanton described the UK health authorities as being in a state of denial in the 1980s about the risks that infected health care workers posed to patients.<sup>11</sup> Only those health care workers who were actually implicated in transmitting hepatitis B had their practice restricted, a principle which was subsequently applied to HIV infected health professionals. In the US, the CDC

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<sup>7</sup> Department of Health, *Hepatitis B and HIV Transmission: Prevention in Health Care Settings*.

<sup>8</sup> *ibid.*, p.9.

<sup>9</sup> DHSS, Expert Advisory Group on AIDS, ‘HIV Infected Health Care Workers’, London, 1988, cited in Hospital Infection Society, ‘Acquired immune deficiency syndrome: Recommendations of a Working Party of the Hospital Infection Society’, *Journal of Hospital Infection*, 15, 1, January 1990, pp.17-34; Department of Health, *Hepatitis B and HIV Transmission: Prevention in Health Care Settings*.

<sup>10</sup> A New Zealand surgeon, who became acutely aware of the occupational risk of exposure to the hepatitis B virus when a surgical colleague became infected in the late 1970s, recalled that, at this time, hepatitis B infection only became an employment issue if compensation was involved. Otherwise, in his experience, the decision over whether to remain in practice was left to the individual health professional. Anonymous source.

<sup>11</sup> J. M. Stanton, ‘Health Policy and Medical Research: Hepatitis B in the UK since the 1940s’, p.236.

took a similar position towards hepatitis B infected workers, and refused to adjudicate on the matter of HIV infected workers. It referred the matter of whether they were safe to perform clinical duties to their personal physicians and employing authorities to determine on a case-by-case basis.<sup>12</sup>

Contemporary historians of hepatitis B and HIV policy have taken a particular interest in the balance struck by the UK and the US health authorities in the 1970s and 1980s in favour of workers' rights. Stanton argued that 'it was almost as if a deal was negotiated imposing strict safety precautions on health workers in return for allowing them to avoid screening [for hepatitis B]'.<sup>13</sup> As discussed in Chapter Three, there were strong economic disincentives against screening. One of Stanton's informants, leading British microbiologist David Dane, contended that if surgeons had been 'threatened by the loss of their professional life as a result of a blood test', they could have demanded that all surgical patients were screened for hepatitis B virus infection at great cost to the health services.<sup>14</sup> Furthermore, the potential loss of highly qualified health professionals to the health workforce was considered a serious deterrent to routine hepatitis B screening.<sup>15</sup>

In the US, William Muraskin claimed that leading doctors and health professionals went so far as to conceal the dangers posed by hepatitis B infected health care workers from the general public so as to prevent the spectre of stigmatisation, and to protect professional careers.<sup>16</sup> While Stanton described Muraskin's approach as 'veering towards conspiracy theory', she acknowledged that he produced a 'clearly delineated thesis on individual rights overwhelming the public health interest'.<sup>17</sup> In the case of AIDS in the UK, Virginia Berridge proposed that a similarly uneven relationship developed between the health professions and the public, where 'the protection of the individual focused on

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<sup>12</sup> CDC, 'Recommendations for prevention of HIV in health-care settings'.

<sup>13</sup> J. M. Stanton, 'Health Policy and Medical Research: Hepatitis B in the UK since the 1940s', p.236.

<sup>14</sup> *ibid.*, p.220.

<sup>15</sup> *ibid.*, p.219.

<sup>16</sup> W. Muraskin, 'The silent epidemic: The social, ethical and medical problems surrounding the fight against hepatitis B', pp.277-98.

<sup>17</sup> J. M. Stanton, 'Health Policy and Medical Research: Hepatitis B in the UK since the 1940s', pp.28-9.

the rights of doctors, both in relation to their own colleagues and in the relationship with the individual patient'.<sup>18</sup>

Whereas no vaccine was developed against HIV, the introduction of an effective vaccine against hepatitis B in 1981 provided the opportunity to protect health care workers against the hepatitis B virus, and to reduce the risk to patients. However, as Chapter Six explained, the vaccine was derived from the blood of hepatitis B carriers and it was rejected by many health care workers in the US and UK because of fears that it was contaminated with the AIDS virus.<sup>19</sup> Further, as previously discussed, the high cost of the plasma-derived vaccine acted as an additional barrier to its use among health care workers in the UK and the US, where hepatitis B was a relatively uncommon disease. In contrast to their overseas counterparts, New Zealand health care workers expressed a strong desire to be immunised, partly as a result of local research that drew attention to the high prevalence of hepatitis B virus infection among the general population.<sup>20</sup>

During the mid-1980s, professional organisations, including the New Zealand Medical Association, made repeated requests to the Health Department to provide hepatitis B vaccine for health care workers.<sup>21</sup> In response, the Department issued a circular which made it clear that employers, i.e. hospital boards, were responsible for staff immunisation.<sup>22</sup> As individual boards had to purchase the vaccine from their limited

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<sup>18</sup> V. Berridge, *AIDS in the UK: The Making of Policy, 1981-1994*, p.220.

<sup>19</sup> For further discussion of concerns over the rumoured association between AIDS and the hepatitis B vaccine, see J. M. Stanton, 'What shapes vaccine policy? The case of hepatitis B in the UK', p.432; CDC, 'Hepatitis B vaccine: evidence confirming lack of AIDS transmission', pp.685-7; P. A. Offit, *Vaccinated: One Man's Quest to Defeat the World's Deadliest Diseases*, p.136.

<sup>20</sup> In 1985, Guy Hawley, Deputy Medical Superintendent-in-Chief, Auckland Hospital Board, stated that 'almost every group of health services professionals are expecting to receive hepatitis B vaccine free of charge ... from this hospital board.' Hawley to Director, Division of Hospitals, 'Hepatitis B Vaccine', 6 August 1985, ABQU 632 W4452 697 131/171/1, 58958, ANZW.

<sup>21</sup> Broadfoot to DGH, 'Vaccination against hepatitis B', 3 July 1985, ABQU 632 W4452 697 131/171/1 58958, ANZW.

<sup>22</sup> Department of Health, Circular Letter (Hosp) No. 1985/167, December 1985, 'Vaccine for At-Risk Health Care Workers', ZABV A1073 96c, ANZA; Minister of Health, NZPD, 20 August 1985, p.6422; Minister of Health, NZPD, 18 September 1985, ABQU 632 W4452 697 131/171/1 58958, 1985, ANZW.

operational funds, immunisation policies varied widely.<sup>23</sup> In mid-1987, 17 of the 22 boards provided immunisation for their high-risk staff, and of those boards, seven used one-tenth to one-half of the recommended adult dose of vaccine as a cost-saving measure.<sup>24</sup> The Health Department did not publish a comprehensive policy on the use of the vaccine for occupational groups until early 1989, when the price of the vaccine was falling as a result of new production methods and competitive marketing between manufacturers.<sup>25</sup>

To summarise, during the 1980s, workplace policies continued to focus on the occupational risk of blood borne viruses, while the risks to patients were described as extremely rare. Professional organisations did not challenge the ethical aspects of this approach; on the contrary, freedom to practice was seen as the paramount issue. The hepatitis B vaccine presented an effective means of reducing the risks of acquiring and transmitting the hepatitis B virus in the health care setting, but the high cost of the vaccine limited its early use among health care workers.

### **The impact of the ‘case of the Florida dentist’<sup>26</sup>**

In mid-1990, the CDC reported the possible transmission of HIV from an infected health care worker to a patient.<sup>27</sup> By mid-1993, subsequent reports confirmed that a total of six patients had been infected with HIV by Dr David Acer, a Florida dentist.<sup>28</sup> This unprecedented case, which was the subject of close scrutiny by the CDC, the US Congress, health professionals and the media, led to a public outcry over the need for protection from HIV infected health professionals, and to the development of

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<sup>23</sup> In mid-1985, Guy Hawley estimated it would cost the Auckland Hospital Board just under \$1 million to vaccinate its at-risk workforce, ‘Health workers must pay for own protection’, NZH, 20 June 1985.

<sup>24</sup> L. Keene, ‘Hepatitis B: are you at risk?’, *NZ Nursing Journal*, June 1987, pp.22-3. A New Zealand study conducted in late 1984 had shown that adequate levels of immunity could be achieved using low dose hepatitis B immunisation in young adults. P. N. Goldwater, D. G. Woodfield, ‘Successful short course for intradermal hepatitis B vaccine’, *NZMJ*, 97, 26 December 1984, pp.905-6.

<sup>25</sup> Department of Health, *Policy on Hepatitis B Vaccination for Occupational Groups*, Wellington, 1989.

<sup>26</sup> J. Palca, ‘The case of the Florida dentist’, *Science*, 255, 5043, 26 January 1992, pp.392-4.

<sup>27</sup> CDC, ‘Possible transmission of human immunodeficiency virus to a patient during an invasive dental procedure’, pp.489-93.

<sup>28</sup> CDC, ‘Epidemiologic notes and reports update: Transmission of HIV infection during invasive dental procedures - Florida’, pp.377-81; CDC, ‘Update: investigations of persons treated by HIV-infected health-care workers - United States’, *MMWR*, 42, 17, 7 May 1993, pp.329-31; p.337.

controversial new guidelines in the US for the management of HIV and hepatitis B infected health care workers.<sup>29</sup>

While the ‘case of the Florida dentist’ attracted international attention to the issue of HIV-infected health care workers, it had particular resonance in the US where the AIDS epidemic had hit the hardest. By mid-1990, over 126,000 AIDS cases had been reported to health authorities in the US, whereas 3,150 cases had been notified in the UK, and in New Zealand, with a population of four million, fewer than 200 AIDS cases had been notified.<sup>30</sup> US health officials had assured the public that if they practised ‘safe sex’ and did not share needles they would not acquire AIDS, since HIV was primarily transmitted by sexual activity and illicit drug use. Public confidence in the safety of the US health system was therefore severely shaken by reports of patients being exposed to HIV infection during routine health care. According to one contemporary commentator ‘news [of the Florida cases] sparked widespread fear that engaging in behaviour once thought safe – like going to the doctor or dentist – put one at risk of acquiring the virus’.<sup>31</sup> Furthermore, Kimberley Bergalis, the index case in the Florida investigation, was only 23 years of age when she died of AIDS in late 1991. Her tragic circumstances captured the public imagination, and extracts from her accusatory letter to Florida health officials in April 1991 were widely circulated in the media:

Who do I blame? Do I blame myself? I sure don't. I never used IV drugs, never slept with anyone and never had a blood transfusion. I blame every one of you bastards. Anyone who *knew* that Dr Acer was infected ... and stood by not doing a damn thing about it ... If laws are not formed to provide protection, then my suffering and death was in vain.<sup>32</sup>

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<sup>29</sup> CDC, ‘Possible transmission of human immunodeficiency virus to a patient during an invasive dental procedure’, pp.489-93.

<sup>30</sup> ‘Quarterly Report of the MRC: AIDS Epidemiology Group’, ABQU 632 W4452 Box 1946 372/15/7 73150, ANZW.

<sup>31</sup> M. W. DeBarge, ‘The performance of invasive procedures by HIV-infected doctors: The duty to disclose under the informed consent doctrine’, *Connecticut Law Review*, 25, 1993, pp.991-1026.

<sup>32</sup> B. Kantrowitz, ‘Doctors with AIDS: The right to know’, (Cover story) *Newsweek*, 1 July 1991, pp.48-57, cited in L. H. Glantz, W. K. Mariner, G. J. Annas, ‘Risky business: Setting public health policy for HIV-infected health care professionals’, *Milbank Quarterly*, 70, 1, 1992, pp.43-79.



Federal legislators and health authorities responded rapidly to the intense community concern over the potential threat posed by HIV infected health care workers. Politicians, who were sensitive to public demands for infected doctors and dentists to reveal their HIV status, took an aggressive stance on the issue, proposing mandatory testing of all health care workers for HIV, as well as large fines and long jail sentences for health professionals who treated patients without revealing their HIV status.<sup>33</sup> The CDC, which opposed mandatory testing on the grounds that it violated health care worker's rights to privacy and confidentiality, nevertheless recommended that before infected workers performed 'exposure prone procedures', they should disclose their HIV or hepatitis B status to their patients.<sup>34</sup> Despite the CDC stance on mandatory restriction, the disclosure requirement was later critiqued in a *New England Journal of Medicine* editorial as 'amounting to a restriction on practice'.<sup>35</sup>

The US medical profession was deeply divided over the issue of disclosure. While the American Medical Association initially issued guidance in support of the CDC recommendations, the New York State Department of Health published contradictory advice on the grounds that the risk of viral transmission was extremely low.<sup>36</sup> Moreover, the American College of Surgeons expressed concern that the guidelines for HIV positive health care workers 'were not based on scientific data, were not cost-effective, and were intrusive in the extreme'.<sup>37</sup> The CDC recommendations were welcomed outside of the health care community, however; the US Congress subsequently required each state

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<sup>33</sup> Senator Jesse Helm, who sponsored these measures before the US Senate, later wrote that Kimberley Bergalis was his inspiration, and that 'HIV-infected physicians who practice medicine should be treated no better than criminals who gun people down in the street', J. Helm, 'The AIDS-infected physician: Are criminal penalties necessary to protect the public health? Yes, protect innocent victims', *American Bar Association Journal*, 77, October 1991, p.46, cited in L. H. Glantz, W. K. Mariner, G. J. Annas, 'Risky business: Setting public health policy for HIV-infected health care professionals', p.46.

<sup>34</sup> CDC, 'Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures'. According to the 1991 CDC guidelines, 'characteristics of exposure-prone procedures include[d] digital palpation of a needle tip in a body cavity or the simultaneous presence of the health care workers fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic space'.

<sup>35</sup> Anon., 'Editorial: The infected health care provider', *NEJM*, 334, 9, 29 February 1996, pp.594-5.

<sup>36</sup> N. Daniels, 'HIV infected health professionals: public threat or public sacrifice', *Milbank Quarterly*, 70, 1, 1992, pp.3-42.

<sup>37</sup> American College of Surgeons, 'Statement on the surgeon and HIV infection [ST-13]', last updated May 2004, online, available at: [http://www.facs.org/fellows\\_info/statements/st-13.html](http://www.facs.org/fellows_info/statements/st-13.html) (28 April 2009).

legislature to adopt either the CDC guidelines or similar regulations for infected health care workers who performed invasive procedures.<sup>38</sup>

The revised CDC guidelines, which were published in July 1991, made recommendations on the management of both HIV and hepatitis B infected health care workers. Dentists and surgeons, the professional groups implicated most frequently in the spread of the hepatitis B virus, were the obvious targets of the guidelines, which recommended that all health care workers who performed exposure prone procedures should know their HIV and their hepatitis B 'e' antigen status.<sup>39</sup> Almost all reported cases of hepatitis B transmission had involved hepatitis B e antigen positive health care workers, and both e antigen positive and HIV positive workers were advised to seek the guidance of an 'expert panel' of local medical specialists about restrictions they should observe in clinical practice. The CDC recommended that the panel should 'include experts who represent a balanced perspective', presumably on medical matters, as no lay representatives were included, and panel members were urged to 'recognise the importance of confidentiality and the privacy rights of infected health care workers'.<sup>40</sup>

The CDC guidelines emphasised the use of 'universal precautions' during clinical activities, explaining that the majority of reports of hepatitis B virus transmission in the US occurred 'before awareness increased of the risks of transmission of blood-borne pathogens in health-care settings and before emphasis was placed on the use of universal precautions and hepatitis B vaccine among [health care workers]'. Despite this assertion, however, the CDC was neither willing to endorse mandatory hepatitis B immunisation for health care workers nor to confront the limitations of personal protective equipment such

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<sup>38</sup> United States Congress, Section 633 of Public Law 102-141, 1991. Individual states introduced different versions of the legislation, with some states such as Illinois and Minnesota adopting the mandatory disclosure clause and others such as New York, Alaska, Arizona, Maine Michigan, North Dakota, Wisconsin, and Florida taking a strong stance on universal precautions and infection control education for health care workers. S. L. DiMaggio, 'State regulations and the HIV-positive health care professional: A response to a problem that does not exist', *American Journal of Law and Medicine*, XIX, 4, 1993, pp.497-522.

<sup>39</sup> 'The presence of hepatitis B e antigen in the blood indicates a high degree of infectivity i.e. an actively replicating virus', Ministry of Health, *Immunisation Handbook 2006*, p.126.

<sup>40</sup> CDC, 'Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures', p.4.

as surgical gloves, stating only that ‘the routine use of gloves does not prevent most injuries caused by sharp instruments and does not eliminate the potential for exposure of a patient to a health care worker's blood and transmission of [the hepatitis B virus]’.<sup>41</sup>

On paper, the responses of the CDC and the US legislature signalled a more assertive approach to the management of hepatitis B and HIV infected health care workers, and an intention to recalibrate the balance between the rights of health care workers and the rights of patients. In reality, however, inconsistencies in state legislation, and the lack of mandatory hepatitis B testing and immunisation meant that the CDC recommendations had limited effect. Health care workers could respond in several different ways; they could choose to comply, they could conceal their infected status, or they could choose not to be tested and remain ignorant of their infective status.

Events in Florida also influenced the development of new UK guidelines for HIV infected health care workers, but these were markedly different from those introduced in the US. In early 1991, the *Communicable Disease Report Weekly* (CDR Weekly), which provided public health information for England and Wales, summarised the extensive investigation undertaken by the CDC into the case of the Florida dentist.<sup>42</sup> It referred readers to the UK guidelines for the management of HIV infected health care workers published in 1988 by the Expert Advisory Group on AIDS (EAGA).<sup>43</sup> The UK health authorities were already sensitised to the media response to HIV infected health care workers; Virginia Berridge explained that EAGA had developed the 1988 guidelines after the media ‘suddenly woke up to the fact that the spread of HIV among the general population might also include spread among the medical profession as well’.<sup>44</sup> She

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<sup>41</sup> *ibid.*, p.3.

<sup>42</sup> The CDR Weekly was the national public health bulletin for England and Wales from 1991 to 2007, when it was superseded by the *Health Protection Report*. Online, nd, available at: <http://www.hpa.org.uk/cdr/default.htm> (21 June 2009).

<sup>43</sup> The Expert Advisory Group on AIDS (EAGA) was established in 1985 as a non-departmental public body to provide advice on HIV/AIDS to the Department of Health, online, nd, available at: <http://www.dh.gov.uk/ab/EAGA/index.htm> (24 June 2009); Expert Advisory Group on AIDS, ‘AIDS: HIV-infected health care workers’, London, March 1988, cited in Anon., ‘Transmission of HIV-1 infection during an invasive dental procedure- United States’, *CDR Weekly*, 1, 5, 1 February 1991, p.1.

<sup>44</sup> Virginia Berridge explained that in November 1987, the tabloid *News of the World* threatened to publish the names of two doctors being treated for AIDS at St Mary’s Hospital in London. Sir Donald Acheson,

described growing media and political pressure during the late 1980s to introduce HIV screening for health care workers.

In December 1991, EAGA completely revised its earlier recommendations, and introduced radical new restrictions on the practice of HIV infected health professionals. No HIV-positive health care worker was to perform 'invasive surgical procedures in which injury to the worker could result in blood contaminating the patient's open tissues'.<sup>45</sup> At the same time, the Department of Health established a United Kingdom Advisory Panel under the direction of EAGA to consider individual cases of HIV infected health care workers and ensure national consistency in the implementation of the new policy.

Unlike the CDC, the UK Department of Health was empowered to act as a national authority on matters concerning health care workers. While the number of HIV infected health professionals in the UK, and hence the risk to patients, was likely to be much lower than in the US, there was heightened political awareness of the problem, and after the first case of HIV transmission was confirmed by the CDC, the UK health authorities acted decisively in the interests of public safety.<sup>46</sup> Even though the Department of Health and its advisory committees were in agreement with the CDC over the importance of universal precautions in the clinical setting, they maintained that additional restrictions were warranted to manage the small, but real, risk to patients from HIV infected health care workers.

In New Zealand, in contrast to the UK, the Health Department gave no indication of revising its official stance on HIV and hepatitis B infected health care workers. In 1991,

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Chief Medical Officer of the UK Department of Health, warned Cabinet that 'if public pressure for screening was acceded to, then the profession would retaliate by demanding screening for their patients'. V. Berridge, *AIDS in the UK: The Making of Policy, 1981-1994*, pp.216-7.

<sup>45</sup> UK Department of Health, 'AIDS- HIV-infected health care workers: Occupational guidance for health care workers, their physicians and employers', London, December 1991, cited in Anon., 'HIV infected health care workers', *CDR Weekly*, 1, 49, 6 December 1991, p.1.

<sup>46</sup> In mid-1991, *Time* magazine claimed that 170 dentists and 730 physicians were known to have AIDS in the US. C. Gorman, 'Should you worry about getting AIDS from your dentist?', *Time*, 138, 4, 29 July 1991, pp.50-1.

the Department was distracted by problems surrounding hepatitis C, another blood borne virus that posed a risk to transfusion recipients. Hepatitis C virus, previously known as non-A non-B hepatitis, was identified in 1987, and the first screening test became available in 1990. US blood banks began screening blood for hepatitis C in May 1990, and the UK introduced testing in September 1991.<sup>47</sup> Despite strong recommendations from its technical advisory committees to introduce hepatitis C screening in mid-1990, the New Zealand government declined to fund screening until mid-1992, by which time over 500 people had been infected through contaminated blood.<sup>48</sup> As a result of the heightened public and political interest in this issue, the Health Department conducted an official inquiry into the safety of the blood supply.<sup>49</sup>

Previous chapters have discussed the effects of the radical health reforms of the early 1990s on the Health Department's responsiveness to public health concerns. The disruption caused by the reforms may also have contributed to departmental inaction on the issue of infected health care workers.<sup>50</sup> Despite the interest in the issue within the wider health professions, updating the 1989 guidelines was not a departmental priority, and other groups stepped in to fill the policy vacuum. In Auckland, for example, in 1991, in response to concerns raised by the 'Florida dentist ... [and] several instances of transmission of hepatitis B [that] have occurred in recent years', Auckland Medical School developed guidelines for medical students 'to inform them of the risks of transmitting hepatitis B or HIV infection to their patients, and to advise them of the most effective methods of preventing such transmission'.<sup>51</sup>

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<sup>47</sup> J. G. Donahue, A. Munoz, P. M. Ness, D. E. Brown, D. H. Yawn, H.A. McAllister, B. A. Reitz, K. E. Nelson, 'The declining risk of post-transfusion hepatitis C virus infection', *NEJM*, 327, 6, 6 August 1992, pp.369-73; Anon., 'Surveillance of viral infections in donated blood', *CDR Weekly*, 14, 44, 28 October 2004, <http://www.hpa.org.uk/CDR/archives/2004/cdr4404.pdf> (24 June 2009).

<sup>48</sup> P. Howden-Chapman, 'Blood-ties: accountability for blood quality in New Zealand', *Health Policy*, 27, 1994, pp.35-51.

<sup>49</sup> Department of Health, *Inquiry into matters relating to the safety of blood products in New Zealand*, Wellington, 1992.

<sup>50</sup> Philippa Howden-Chapman, a sociologist and senior lecturer in public health at the Wellington School of Medicine, attributed the delay in introducing hepatitis C screening to the fact that the problem emerged 'over the period the health reforms were introduced [when] there was a move away from public and community health, a change of government and a move away from no-fault compensation'. 'Hepatitis C patients draw shortest straw', *New Zealand Doctor*, 30 October 1996, p.16.

<sup>51</sup> M. G. Thomas, 'Guidelines for health care workers who have hepatitis B virus or human immunodeficiency virus infection', *NZMJ*, 105, 11 March 1992, pp.86-7.

The Medical School made a number of recommendations for health care workers infected with hepatitis B and HIV which centred on voluntary testing, professional rights and responsibilities, and careful adherence to universal precautions. Health care workers with an increased likelihood of HIV or hepatitis B carriage ‘had a responsibility’ to be tested for hepatitis B, and if infected, for the hepatitis B e antigen. Those who were HIV or hepatitis B e antigen positive were counselled to ‘consider employment in an area where the risk of a patient being exposed to their blood or body fluids is low’.<sup>52</sup> In tacit acknowledgment of the lack of departmental guidance, the guidelines were published in the *New Zealand Medical Journal* as a useful example for individuals and other institutions to follow.

Thus, from 1991, the US and the UK policies diverged: whereas the CDC maintained that voluntary limitations on professional activity and the use of universal precautions was sufficient to ensure patient safety, the UK regarded mandatory restrictions as a necessary incursion on the rights of infected health workers to protect patients from the low but documented risk of HIV transmission. In New Zealand, concerns about the implications of blood borne viruses were raised within the medical profession, but the Health Department showed no signs of acknowledging the events in the US or the UK, or of updating its guidelines on HIV or hepatitis B infected health care workers.

### **Guidelines for hepatitis B infected health care workers**

In the UK, the debate over HIV infected health care workers coincided with two official investigations into hepatitis B virus transmission from surgeons to their patients. Public interest in such cases, which had been stimulated by fears over HIV transmission, added increased pressure for a decisive policy response.<sup>53</sup> After introducing the revised HIV policy, health authorities turned their attention to addressing the problem of hepatitis B infected health care workers.

In 1990, the UK Department of Health became aware of two separate outbreaks of hepatitis B virus infection associated with infected surgeons. As Jennifer Stanton

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<sup>52</sup> *ibid.*, p.87.

<sup>53</sup> W. Irving, email communication, 4 August 2009.

explained, health officials were particularly disturbed to learn of a cardiac surgical registrar who had claimed to be immune to hepatitis B before beginning work in the UK. The registrar, who was subsequently found to be hepatitis B e antigen positive, infected two patients despite careful adherence to universal precautions. An internal hospital inquiry concluded that the existing guidelines had mistakenly weighted ‘the balance in favour of the rights of the individual surgeon to keep his carrier state confidential, against the public health interest’.<sup>54</sup> Members of the inquiry panel recommended that the Department of Health revise the official guidelines on infected health care workers as soon as possible.

Prompted by these outbreaks, Dr Julia Heptonstall, who was responsible for hepatitis surveillance in England and Wales, undertook a retrospective review of surgery-related hepatitis B infections. She identified twelve hepatitis B outbreaks between 1975 and 1990 involving 91 patients, although she estimated the true total of affected patients to be closer to 200. Heptonstall was aware of five cases of acute hepatitis B virus infection among UK surgeons between 1985 and 1990, none of whom had completed courses of hepatitis B vaccine, while studies of vaccine uptake among UK surgeons suggested that immunisation rates varied between 60 and 90 per cent. The reasons given by surgeons for vaccine refusal included ‘fear of needles, lack of concern, and the belief that “being infected with [the hepatitis B virus] was God’s punishment for sloppy surgery”’.<sup>55</sup> In her report on the outbreaks, published in 1991, Heptonstall suggested that instead of waiting for more outbreaks to occur, hepatitis B e antigen positive surgeons as well as those who did not respond to hepatitis B immunisation should be ‘asked to desist’ from invasive surgical procedures.<sup>56</sup>

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<sup>54</sup> J. M. Stanton, ‘Health Policy and Medical Research: Hepatitis B in the UK since the 1940s’, pp.220-1.

<sup>55</sup> J. Heptonstall, ‘Outbreaks of hepatitis B virus infection associated with infected surgical staff’, *CDR Review*, 1, 19 July 1991, p.84.

<sup>56</sup> *ibid.*, p.85; Not all people respond to hepatitis B vaccine; approximately 10 per cent of healthy adults do not develop immunity, although ‘some non-responders to the initial vaccination course will produce adequate antibody levels after a further booster dose of vaccine, or a second course [of vaccine]’, Ministry of Health, *Immunisation Handbook 2006*, p.132.

In August 1993, the Advisory Group on Hepatitis (AGH) published revised UK guidelines for hepatitis B infected health care workers. Known as the ‘Olive Book’, the guidelines were formally entitled ‘Protecting Health Care Workers and Patients from Hepatitis B’.<sup>57</sup> The Olive Book took a radically different stance from the CDC on hepatitis B testing, immunisation, and practice restriction. All health care workers who performed exposure prone procedures were to be immunised against hepatitis B. Those that did not respond to immunisation were then tested for their hepatitis B carrier status. No hepatitis B e antigen positive health care workers were to perform exposure prone procedures.<sup>58</sup> All surgeons were to be tested and immunised by mid-1994, and all other staff involved in exposure prone procedures tested and immunised by mid-1995.<sup>59</sup> Medical, dentistry, nursing and midwifery students were also required to be vaccinated and tested for immunity before they performed exposure prone procedures.<sup>60</sup>

The greatest impact of the restrictions fell on surgeons, whose work made them most vulnerable to hepatitis B virus infection. As Dr Will Irving, a UK virologist and later chair of AGH, explained, ‘the implementation of [the 1993] guidance undoubtedly had a profound effect on those surgeons found to be [hepatitis B] e antigen positive who were faced with the end of their surgical careers’.<sup>61</sup> The guidelines also had a significant effect on the health services, primarily through the loss of surgical expertise. To manage the complex medical, professional and ethical issues involved, the remit of the UK Advisory Panel on HIV infected health care workers was extended under the new title of the UK

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<sup>57</sup> UK Department of Health, Advisory Group on Hepatitis (AGH), *Protecting Health Care Workers and Patients from Hepatitis B*, London, 1993, p.4, online, available at: [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4079307.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4079307.pdf) (13 February 2009).

<sup>58</sup> AGH defined exposure prone procedures as ‘those where there is a risk that injury to the worker may result in the exposure of the patient’s open tissues to the blood of the worker. These procedures include those where the worker’s gloved hands may be in contact with sharp instruments, needle tips and sharp tissues (spicules of bone or teeth) inside a patient’s open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times’. *ibid.*, p.5.

<sup>59</sup> National Health Service (NHS) Executive, to Chief Executives of NHS Trusts and Health Authorities, EL (96) 77, 26 September 1996, Addendum to HSG (93)40: Protecting health care workers and patients from hepatitis B - EL (96) 77, online, available at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Executiveletters/DH\\_4088385](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Executiveletters/DH_4088385) (20 March 2009).

<sup>60</sup> UK Department of Health, AGH, *Protecting Health Care Workers and Patients from Hepatitis B*, p.4.

<sup>61</sup> W. Irving and K. Harling, ‘Occupational Aspects of Hepatitis’, in H. C. Thomas, S. Lemon, and A. J. Zuckerman, eds, *Viral Hepatitis*, 3<sup>rd</sup> edn, Oxford, 2005, p.704.



Advisory Panel for health care workers infected with bloodborne viruses (UKAP). The panel consisted of a range of medical experts, representatives from surgery, dentistry, nursing and midwifery, as well as several lay members and an ethicist.<sup>62</sup>

The proactive approach taken by the UK towards the management of infected health care workers appeared to make little impression on the New Zealand health authorities. Health Department inaction led professional bodies such as the Medical Council of New Zealand to provide guidance on an ad hoc basis. In December 1993, the Medical Council, which is responsible for maintaining standards of medical care, issued a policy statement on the transmission of ‘major viral infections’.<sup>63</sup> The council encouraged doctors to seek testing if they suspected they had been exposed to either HIV or hepatitis B, because there ‘might be a need to restrict practice’. It appealed to doctors to practise ethically: ‘it could be professional misconduct for an infected doctor to put a patient at risk’. Nevertheless, it did not recommend mandatory hepatitis B testing and immunisation, or patient disclosure of the health care worker’s infective status, stating only that requiring HIV or hepatitis B e antigen positive medical students to inform patients of their status would be ‘a deterrent to voluntary testing and an infringement to privacy and confidentiality’.<sup>64</sup>

Why did the Medical Council choose a weak policy of voluntary hepatitis B testing and immunisation when the UK had acted so decisively in favour of minimising the risks of hepatitis B transmission to patients? Stanton described the influence of local outbreaks on UK policy, which led to a greater emphasis on the risks to patients rather than the needs of health care workers.<sup>65</sup> In the US, the hostile public reaction to reports that an HIV

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<sup>62</sup> Additional information on UKAP is listed on the UK Health Protection Agency website, online, nd, available at: <http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/1203496960618?p=1203496960618#1> (25 June 2009).

<sup>63</sup> Medical Council of New Zealand (MCNZ), ‘The Medical Council and transmission of major viral infections’, NZMJ, 106, 10 November 1993, p.482. The MCNZ registers doctors to practice in New Zealand, and carries responsibilities in the areas of medical standards and doctors’ conduct and competence. MCNZ, ‘About Us’, online, nd, available at: <http://www.mcnz.org.nz/AboutUs/Whatwedo/tabid/287/Default.aspx> (2 April 2009).

<sup>64</sup> *ibid.*

<sup>65</sup> J. M. Stanton, ‘Health Policy and Medical Research: Hepatitis B in the UK since the 1940s’, pp.219-24. Julia Heptonstall’s 1991 report and subsequent instances of surgeon-to-patient transmission, including a sensational case that came to light in August 1993 of a cardiac surgeon who substituted patients’ blood for

positive dentist had infected six patients led to the revision of CDC recommendations, and the introduction of disclosure requirements. In New Zealand, where no such events were recorded, it appeared that the Medical Council was unconvinced that such steps were warranted.

While the risk of HIV transmission was remote in New Zealand, given the low prevalence of HIV, in the early 1990s, New Zealand had a higher prevalence of hepatitis B than other western countries. On the basis of local prevalence studies, Maori health practitioners, who were relatively low in numbers and whose increasing presence in the health workforce was seen as vital for the provision of Maori-led health services, were more likely to be hepatitis B carriers than their Pakeha counterparts.<sup>66</sup> Furthermore, medical immigrants to New Zealand came from a variety of countries, some of which had a high prevalence of hepatitis B.<sup>67</sup> Quite apart from the pressure that professional organisations may have exerted to maintain the status quo, New Zealand had less ability than the US or UK to recruit highly qualified clinicians if hepatitis B carriers were removed from ‘hands-on’ care. These and other factors may have influenced the council’s cautious approach to testing and practice restrictions.

### **Conflicting views on mandatory immunisation and practice restriction**

During the late 1990s, despite mounting evidence of hepatitis B, hepatitis C and HIV transmission, neither the US nor New Zealand adopted policies similar to those developed in the UK to protect patients from infected health care workers. The hepatitis B vaccine presented an obvious means of reducing the risk of hepatitis B virus infection among health care workers and patients. Nonetheless, the US and New Zealand both rejected the UK model of mandatory hepatitis B screening and immunisation of high risk health care workers, with its connotations of practice restriction.

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his own to escape detection as a hepatitis B carrier, and who subsequently infected at least 24 patients, also undoubtedly influenced public and professional opinion on mandatory testing and practice restriction in the UK. See for example, C. Dyer, ‘Surgeon jailed for infecting patients’, *British Medical Journal*, 309, 6959, 8 October 1994, p.896.

<sup>66</sup> For a discussion of Maori workforce development and the health services from 1984 – 2000, see for example, A. Gillies, ‘Kia Taupunga te Ngaukau Maori: Anchoring Maori Health Workforce Potential’, PhD thesis, Massey University, 2006.

<sup>67</sup> Table 3, ‘Risk of transmission of [hepatitis B virus] by prevalence band of country of origin of [health care worker]’, in W. Irving and K. Harling, ‘Occupational Aspects of Hepatitis’, p.731.

In February 1996, the *New England Journal of Medicine* reported the first known instance of health care worker-associated hepatitis C transmission, from a Spanish cardiac surgeon with chronic hepatitis C to five of his patients, infected during open heart surgery. In the same issue, CDC investigators described the case of a hepatitis B infected thoracic surgeon in the US who had infected 19 patients.<sup>68</sup> In the UK, in August 1996, Julia Heptonstall reported 20 cases of acute hepatitis B among the patients of an infected cardiac surgeon who had deliberately deceived the health authorities over his carrier status.<sup>69</sup> In late 1996, a CDC serosurvey of US orthopaedic surgeons was published; only 65 per cent of surgeons surveyed reported that they had been immunised against hepatitis B.<sup>70</sup> In early 1997, the second known instance of health care worker to patient transmission of HIV was reported in France, and evidence of hepatitis B transmission to patients from four hepatitis B e antigen negative surgeons was published in the US.<sup>71</sup> These and other reports revived debate over the management of infected health care workers, and drew attention to the relative frequency with which hepatitis B was transmitted in the health care setting.

Proposals to prevent the problem of hepatitis B transmission varied, however, and they were largely derived from the policy positions established in the early 1990s. In the US, public and professional anxiety about HIV continued to dominate policy responses. As a result, proposals to screen health care workers to ascertain their hepatitis B status before

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<sup>68</sup> J. L. Esteban, J. Gomez, M. Martell, B. Cabot, J. Quer, J. Camps, A. Gonzalez, T. Otero, A. Moya, R. Esteban, J. Garcia, 'Transmission of hepatitis C by an infected surgeon', pp.555-60; R. Harpaz, L. Von Seidlein, F. M. Averhoff, M.P. Tormey, S. D. Sinha, K. Kotsopoulou, S. B. Lambert, B. H. Robertson, J. D. Cherry, C. N. Shapiro, 'Transmission of hepatitis B virus to multiple patients from a surgeon without evidence of inadequate infection control', *NEJM*, 334, 9, 29 February 1996, pp.549-54.

<sup>69</sup> J. Heptonstall, 'Lessons from two linked clusters of acute hepatitis B in cardiothoracic surgery patients', *CDR Weekly*, 6, 9, 16 August 1996, pp.119-25. The cardiac surgeon provided the blood of a hepatitis B immune individual in place of his own during the initial outbreak investigation. This led to recommendations for a change in policy: during investigations, blood samples were to be collected directly from the surgical team involved regardless of previous laboratory results.

<sup>70</sup> C. N. Shapiro, J. I. Tokars, M. Chamberland, 'Use of the hepatitis B vaccine and infection with hepatitis B and C among orthopaedic surgeons', *Journal of Bone and Joint Surgery*, 78-A, 12, December 1996, pp.1791-1800. Among the 3239 US surgeons surveyed, older surgeons (35 per cent) were less likely than surgeons under 30 years of age (90 per cent) to report hepatitis B immunisation.

<sup>71</sup> AIDS/TB Committee of the Society for Healthcare Epidemiology of America (SHEA), 'SHEA Position Paper: Management of health care workers infected with hepatitis B virus, hepatitis C virus, human immunodeficiency virus, or other bloodborne pathogens', *Infection Control and Hospital Epidemiology*, 18, 5, May 1997, pp.349-61; The Incident Team and Others, 'Transmission of hepatitis B to patients from four infected surgeons without hepatitis B e antigen', *NEJM*, 336, 3, 16 January 1997, pp.178-84.

immunisation were inevitably associated with the contentious issue of screening for HIV, and with practice restrictions. In 1997, the CDC strongly recommended hepatitis B immunisation among health care workers performing tasks involving exposure to blood or 'blood-contaminated body fluids', but it stated clearly that pre-immunisation screening to establish immune status was not indicated. The CDC would not support testing regimens that revealed hepatitis B carriers, or the small percentage of health care workers who did not respond to immunisation, and who were therefore still at risk of acquiring the disease.<sup>72</sup> Its stance was supported by the influential Society for Healthcare Epidemiology of America (SHEA) which described mandatory screening of health care workers as 'intrinsically adversarial'.<sup>73</sup>

Throughout the 1990s, US policies continued to focus on the importance of infection control procedures to reduce risk to patients and protect health care workers. In 1997, in regard to hepatitis B e antigen positive health care workers, SHEA recommended they should routinely 'double glove' for patient contact, even though it conceded that these workers should not perform a subset of invasive procedures which 'despite the appropriate use of barriers and infection control procedures have been linked epidemiologically to provider-to-patient transmission (e.g. vaginal hysterectomy, major pelvic procedures, cardiac surgery)'.<sup>74</sup> SHEA gave no guidance on hepatitis B immunisation, and in 1998, as a result of the controversy surrounding the management of infected health care workers the CDC put planned revisions to its 1991 guidelines on hold indefinitely.

The policy stalemate in the US provoked a small but determined lobby to voice the need for coherent national guidelines like those of the UK, in order to achieve a better balance between protecting the rights of infected health care workers and protecting the public. In

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<sup>72</sup> Recommendations of the Advisory Committee on Immunization Practices (ACIP), and the Hospital Infection Control Practices Advisory Committee (HICPAC), 'Immunization of Health-Care Workers', *MMWR*, 46, RR-18, 26 December 1997, pp.1-42.

<sup>73</sup> AIDS/TB Committee of the Society for Healthcare Epidemiology of America, 'SHEA Position Paper: Management of health care workers infected with hepatitis B virus, hepatitis C virus, human immunodeficiency virus, or other bloodborne pathogens', p.361.

<sup>74</sup> *ibid.*, pp.349-51.

late 1998, in the *Lancet*, US physicians Elaine Ristinen and Ravinder Mamtani condemned the CDC for allowing policy for hepatitis B infected health care workers to languish ‘despite accumulating evidence that transmission of hepatitis from health-care workers to patients may be a greater risk than estimated in 1991’. Progress on these matters had stalled, they claimed, because the issue of practice restriction had ‘evidently been so delicate that it seems to have been largely avoided’. <sup>75</sup>

In 1999, Patti Miller Tereskerz, Richard Pearson and Janine Jagger, public health physicians at the University of Virginia, described the issue in more dramatic terms: ‘a conflict of life versus livelihood’. <sup>76</sup> In the US, under the CDC guidelines, unlike the UK where a national body (UKAP) with multidisciplinary and lay membership ensured a balanced representation of professional and patient rights, infected health care workers were regulated by their own colleagues. Tereskerz, Pearson and Jagger argued that this structure created ‘a serious conflict of interest ... Faced with a decision to limit an infected colleague’s practice, health professionals must be aware that their decisions could affect their own ... livelihoods in the future’. <sup>77</sup> To address this imbalance, they proposed a more representative multidisciplinary committee, such as the National Bioethics Advisory Committee, which included representatives from the professions of ethics, law, and medicine, as well as the wider community, to develop a national policy that protected all involved parties.

In New Zealand, by contrast, there were no such vocal advocates for policy change. Professional organisations, such as the Royal Australasian College of Surgeons (RACS), were willing to work within existing Medical Council policy, which placed no undue restrictions on professional autonomy. RACS, which represented both New Zealand and Australian surgeons, had a much larger Australian membership. <sup>78</sup> In the 1970s and 80s,

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<sup>75</sup> E. Ristinen, R. Mamtani, ‘Effects of transmission of hepatitis B virus by health-care workers’, *Lancet*, 352, 9137, 24 October 1998, pp.1381-3.

<sup>76</sup> P. M. Tereskerz, R. D. Pearson, J. Jagger, ‘Infected physicians and invasive procedures: National policy and legal reality’, *Milbank Quarterly*, 77, 4, 1999, p.511.

<sup>77</sup> *ibid.*, p.525.

<sup>78</sup> As of 31 December 2008, there were 3841 ‘active Fellows’ of the college in Australia and 668 in NZ, RACS, ‘Who we are’, online, nd, available at:

hepatitis B virus infection in Australia was generally confined to the indigenous population, many of whom lived in remote communities, and to small numbers of drug users and homosexual men, so that the disease presented less of a concern for Australian surgeons than for their New Zealand counterparts.<sup>79</sup> Like the Medical Council, RACS supported voluntary adherence to practice restrictions, hepatitis B testing, and immunisation. Bold capitals in the college handbook *Infection Control in Surgery*, published in mid-1998, emphasised the importance of immunisation: ‘ALL STAFF IN THE SURGICAL TEAM SHOULD BE VACCINATED FOR HEPATITIS B’.<sup>80</sup> Nonetheless, RACS did not promote mandatory testing to ascertain hepatitis B status or a policy of mandatory hepatitis B immunisation.

In a more detailed discussion of infection control, RACS acknowledged that the development of public health policies for HIV, hepatitis B and C had ‘at times created conflict between the rights of the community and those of individuals’, but explained that their policy document ‘aim[ed] to strike a sensible balance in this area’. RACS described the inherent risks of transmitting blood borne viruses in surgery: ‘Surgeons have always run the risk of contracting disease from the very people they are trying to help. Unhappily, the converse is true; surgeons on occasions transmit diseases to their patients.’ Even though it claimed that hepatitis B virus infection among surgical staff ‘should now be a rarity’, the college conceded that ‘in spite of the effectiveness of the vaccine, uptake of Hepatitis B vaccine ... remains unacceptably low’.<sup>81</sup> In New Zealand, where hepatitis B was relatively common, maintaining a policy of voluntary hepatitis B immunisation provided little protection for surgeons or their patients.

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<http://www.surgeons.org/Content/NavigationMenu/WhoWeAre/Regions/NZ/default.htm#office> (8 July 2009).

<sup>79</sup> In June 2006, the estimated resident Indigenous population of Australia was 517,000 people, or 2.5% of the total Australian population. Australian Bureau of Statistics website, online, nd, available at: [http://www.abs.gov.au/websitedbs/D3310114.nsf/home/home?opendocument?utm\\_id=GT](http://www.abs.gov.au/websitedbs/D3310114.nsf/home/home?opendocument?utm_id=GT) (8 July 2009).

<sup>80</sup> RACS, Advisory Committee on Infection Control in Surgery, *Infection Control in Surgery*, Melbourne, 1998, p.40.

<sup>81</sup> RACS, ‘Policies - Infection Control in Surgery’, July 1998, online, nd, available at: [http://www.surgeons.org/Content/NavigationMenu/CollegeResources/Publications/Infection\\_Control.pdf](http://www.surgeons.org/Content/NavigationMenu/CollegeResources/Publications/Infection_Control.pdf) (24 April 2009).

In December 1998, the Medical Council of New Zealand issued revised guidelines for major transmissible viral infections. Like the CDC, the council placed strong emphasis on the importance of universal precautions in preventing hepatitis B virus, hepatitis C virus and HIV transmission in health care settings. It recommended rather than required doctors who performed exposure prone procedures to be tested to determine their HIV and hepatitis B status, and if infected, to seek the advice of a local panel of medical experts which made decisions to restrict clinical practice on a case-by-case basis.<sup>82</sup> For non-immune doctors, the council recommended that hepatitis B immunisation ‘should be encouraged’.<sup>83</sup> In respect of requiring doctors to inform patients that they themselves were infected, however, its advice differed from CDC guidance. According to the Medical Council, mandatory disclosure ‘would only serve as a deterrent to doctors seeking voluntary testing and medical evaluation. A doctor, like any other person, has a right to privacy and confidentiality where there is no risk to the public’.<sup>84</sup>

In the late 1990s, then, despite evidence of continued hepatitis B transmission in the UK and US and studies revealing less than adequate vaccine uptake among surgeons, neither the CDC, nor the New Zealand Medical Council, was willing to adopt the UK policy of mandatory testing and hepatitis B immunisation. The CDC had no mandate to enforce practice restrictions on infected health care workers; however, by deferring its planned policy revision its critics claimed that it reduced the opportunity for meaningful discussion, and hampered attempts to achieve a policy consensus. In New Zealand, where the debate over infected health care workers was largely conducted among senior members of the medical and dental professions, the Medical Council continued to promote policy that protected practitioners’ rights.

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<sup>82</sup> In 1998, the MCNZ adopted the Royal Australasian College of Surgeon’s definition of an exposure prone procedure: ‘Exposure prone procedures are characterised by the potential for direct contact between the skin (usually finger and thumb of the doctor) and sharp surgical instruments or needles in body cavities or in poorly visualized or confined body sites including the mouth’. MCNZ, ‘Guidelines on Transmissible Major Viral Infections’, Wellington, 1998, pp.1-2.

<sup>83</sup> *ibid.*, p.1.

<sup>84</sup> *ibid.*, p.2.

## Policy developments post-2000

Post- 2000, the issue of infected health care workers continued to challenge policymakers and health professionals. In the US, where the revision of national policy hit the doldrums, there have been calls for reform from opposing sides of the debate, while the UK's restrictive policies have met with some criticism from health professionals. In New Zealand, a lack of action on the part of the government and the central health authorities has led professional bodies to take the initiative in developing national guidelines for the management of infected health care workers.

In the US, planned revisions to the CDC guidelines on healthcare workers infected with blood borne pathogens remained on hold after 2000, with no projected publication date. Two opposing lobbies emerged among advocates for policy change: one urging improved safety measures in the surgical environment and the removal of practice restrictions, and the other promoting improved surveillance of blood exposures and a greater emphasis on patient protection. Both sides called for future policy to be evidence-based, drawing attention to the practical difficulties of developing policy based on the scant data available when no formal programme of surveillance had been undertaken.<sup>85</sup>

The risk of HIV transmission remained central to policy concerns in the US post-2000. Despite the focus on HIV, however, public health experts on opposite sides of the debate acknowledged that, in practice, hepatitis B infected health care workers posed a significantly greater risk to patients. Not surprisingly, they proposed different strategies to address this problem. For those who regarded the existing CDC guidelines as 'stigmatizing for health care workers', and the risks of hepatitis B transmission as relatively 'rare', such as Professor Lawrence Gostin, a leading exponent of public health law, improved adherence to infection control procedures and safer systems of practice in

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<sup>85</sup> See for example, L. O. Gostin, 'A proposed national policy on health-care workers living with HIV/AIDS and other blood-borne pathogens', *JAMA*, 284, 15, 18 October 2000, pp.1965-70; L. A. Chiarello, D. M. Cardo, 'Preventing transmission of hepatitis B virus from surgeons to patients', *Infection Control and Hospital Epidemiology*, 23, 6, June 2002, pp.301-2; S. Paton, S. Zou, A. Guilivi, 'More should be done to protect surgical patients from intra-operative hepatitis B infection', *Infection Control and Hospital Epidemiology*, 23, 6, June 2002, pp.303-5; J. L. Perry, R. D. Pearson, J. Jagger, 'Infected healthcare workers and patient safety: A double standard', *American Journal of Infection Control*, 34, 5, June 2006, pp.313-9.



surgical settings presented the best solution.<sup>86</sup> For others, such as Jane Perry, Richard Pearson and Janine Jagger, long time advocates for greater public protection, continuing reports of hepatitis B transmission from infection health care workers to patients pointed to the need for more stringent regulations.<sup>87</sup>

Attempts to reach consensus on policy were unsuccessful in the US, but in the UK, national policies to manage HIV and hepatitis B infected health care workers were revised as new technical information emerged, and in response to further incidents of hepatitis B transmission.<sup>88</sup> By 2000, despite the restrictions imposed in 1993, eight surgeons and one house officer had spread hepatitis B to at least fifteen patients, three of whom died of fulminant infection. Further investigations revealed that these doctors were hepatitis B virus e antigen negative, but hepatitis B DNA positive.<sup>89</sup> From 2002 onwards, hepatitis B infected health care workers who were e antigen negative but who had 'viral loads' exceeding 10<sup>3</sup> genome equivalents per ml were prevented from performing exposure prone procedures.<sup>90</sup> The national advisory groups and review panel, introduced

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<sup>86</sup> Professor Lawrence Gostin, an influential exponent of public health law, has argued strongly for a removal of practice restrictions and a focus on 'structural changes to make the health workplace safer for both patients and healthcare workers rather than on identification and management of infected healthcare workers'. L. O. Gostin, 'A proposed national policy on health-care workers living with HIV/AIDS and other blood-borne pathogens', p.1965.

<sup>87</sup> The case of a Dutch surgeon, reported in 2002, was particularly contentious as he had infected 28 patients over four years in spite of using careful infection control techniques. I. J. B. Spijkerman, L. Van Doom, M. H. W. Janssen, C. J. Wijkman, M. A. J. Bilkert-Moolman, R. A. Coutinho, G. Weers-Pothoff, 'Transmission of hepatitis B virus from a surgeon to his patients during high-risk and low-risk surgical procedures during 4 years', *Infection Control and Hospital Epidemiology*, 23, 6, June 2002, pp.306-12.

<sup>88</sup> In the UK, despite the 1993 guidelines, by 2000 nine health care workers were known to have transmitted infection to at least 15 patients, three of whom died of fulminant hepatitis. W. Irving and K. Harling, 'Occupational Aspects of Hepatitis', p.704.

<sup>89</sup> The Incident Team and Others, 'Transmission of hepatitis B to patients from four infected surgeons without hepatitis B e antigen', pp.178-84.

<sup>90</sup> National Health Service Circular 2000/020, 'Hepatitis B Infected Health Care Workers', 23 June 2000, online, available at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH\\_4004553](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4004553) (20 March 2009). In 2003, approximately 42 per cent of these health care workers were allowed to continue exposure prone procedures based on their low DNA level. W. F. Carman, S. O. Cameron, 'Editorial: What should be done about hepatitis-B infected health-care workers', *Journal of Medical Microbiology*, 52, 2003, pp.371-2.

in the early 1990s, remained in place as a structure for policy review, guidance on patient ‘look back’ procedures, and individual case management.<sup>91</sup>

While most UK health care workers appeared to have been supportive of the UK guidelines, some individuals were critical of the ‘unbalanced focus on patient rights’ that they argued characterised UK policies.<sup>92</sup> By 2003, approximately 100 infected health care workers had been barred from performing exposure prone procedures. There was some uncertainty as to how they had dealt with such a major career setback – a 2003 editorial in the *Journal of Medical Microbiology* asked ‘have they been retrained? Are they still practising in the UK? Have they moved to other specialties?’<sup>93</sup> Nevertheless, despite protests from some surgeons and dentists, the UK Advisory Group on Hepatitis (AGH) maintained that their recommendations on practice restriction achieved an acceptable compromise between the public safety and the rights of infected health care workers.<sup>94</sup>

The complex issues surrounding practice restriction, redeployment, retraining and compensation were undoubtedly a factor in the tentative attempts by the New Zealand health authorities to tackle the problem of infected health care workers. In 2001, the New Zealand Ministry of Health proposed to collaborate with the Australian Department of Health and Ageing to develop trans-Tasman protocols on infected health care workers; however, for reasons not clear these plans did not eventuate.<sup>95</sup> This was despite the

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<sup>91</sup> After 2000, the UK Advisory Panel for Health Care Workers Infected with Blood Borne Viruses (UKAP) in close liaison with the UK Advisory Group on Hepatitis (AGH) continued to review policy and provide a national advisory function. ‘Patient notification exercises’ and ‘look back’ procedures follow instances when infected health care workers may have infected patients. They provide an opportunity to notify patients, provide treatment if required, and contribute data towards national surveillance. UK Health Protection Agency, UKAP, ‘Annual Report April 2003–April 2004’, online, nd, available at: [http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1194947413302](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947413302) (4 June 2009).

<sup>92</sup> See, for example, P. Tansley, ‘Letter to the Editor: Infection of patients by bloodborne viruses’, *British Journal of Surgery*, 91, 2004, p.778; P. Tansley, N. Beresford, G. Ladas, P. Goldstraw, M. Dusmet, ‘Infection of patients by bloodborne viruses’, *British Journal of Surgery*, 91, April 2004, pp.395-9. P. Twedell, ‘Letter to the Editor: Bloodborne viruses’, *British Dental Journal*, 199, 3, 13 August 2005, p.128; P. Maund, ‘Letter to the Editor: Double standard?’, J. Hardie, ‘Letter to the Editor: Harsh advice?’, *British Dental Journal*, 199, 8, 8 October 2005, p.483.

<sup>93</sup> W. F. Carman, S. O. Cameron, ‘Editorial: What should be done about hepatitis-B infected health-care workers’, pp.371-2.

<sup>94</sup> W. Irving and K. Harling, ‘Occupational Aspects of Hepatitis’, p.705.

<sup>95</sup> Ministry of Health, *An Integrated Approach to Infectious Disease: Priorities for Action 2002-2006*, p.27. Australia produced its own guidelines for infected health care workers in 2004: Australian

increasing consensus among researchers and health policymakers in the UK, Europe and other countries, for greater restrictions on hepatitis B and C infected health care workers.<sup>96</sup> The Medical Council continued to provide advice for doctors in the absence of a ministry-led initiative, although it had no authority to provide guidance for health care workers in other professions.

In early 2003, the council undertook a review of its guidelines on blood borne viruses.<sup>97</sup> Information gathered from the 21 district health boards (DHBs) around New Zealand revealed an assortment of different policies, which reflected both the lack of national leadership on the issue of infected health care workers, and the contentious nature of the problem. Seven DHBs undertook pre-employment screening for hepatitis B virus infection; although only two indicated that hepatitis B immunity was mandatory for 'some positions'. Work restrictions differed, with several DHBs stating that no restrictions were imposed on infected health care workers, provided 'standard infection control precautions' were followed. The council noted that their 1998 guidelines had been criticised by 'some DHBs as [they] did not provide strong guidance on the question of screening particularly with respect to pre-employment screening and checking the status of those performing exposure prone procedures'.<sup>98</sup>

While the Medical Council observed that the risk of the transmission of blood borne viruses from health care worker to patient was generally low, it acknowledged that hepatitis B virus was more infectious, and preventable. Between 1997 and 2004, sixteen

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Department of Health and Ageing, *Infection Control Guidelines for the Prevention of the Transmission of Infectious Diseases in the Health Care Setting*, Canberra, 2004. Online, available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-2004-cdi2802-htm-cdi2802b.htm> (20 September 2009).

<sup>96</sup> European Consensus Conference, Rome, October 28-29 1999, 'Position Paper: Risk management of HBsAg or anti-HCV positive healthcare workers in hospital', *Digestive and Liver Disease*, 33, 2001, pp.795-802; UK Department of Health, *Hepatitis C Infected Health Care Workers*, London, 2002; European Consensus Group, R. N Gunson, D. Shouval, M. Roggendorf, H. Zaaijer, H. Nicholas, H. Holzmann, A. de Schryver, D. Reynders, J. Connell, W. H. Gerlich, R.T. Marino, D. Tsantoulas, E. Rigopoulou, M. Rosenheim, D. Valla, V. Puro, J. Struwe, R. Tedder, C. Aitken, M. Alter, S. W. Schalm, W. F. Carman, 'Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections in health care workers (HCWs): Guidelines for prevention of transmission of HBV and HCV from HCW to patients', *Journal of Clinical Virology*, 27, 2003, pp.213-30.

<sup>97</sup> MCNZ, 'Major Transmissible Viral Infections (ST5.9)', 19 and 20 October 2004, in private possession.

<sup>98</sup> *ibid.*

doctors had disclosed infection with a blood borne virus to the Health Committee of the Medical Council; of these eight were infected with hepatitis B virus. The council gave consideration to mandatory hepatitis B screening and immunisation, however, the employment issues were daunting: ‘follow up systems would need to be in place for those who tested positive and [then] there is the issue of what to do with doctors who refused to be immunised having demonstrated no antibodies to HBV’.<sup>99</sup>

The Medical Council was aware that it had a crucial role in providing ‘firm guidance ... where there is risk of transmission of viral infections from doctors to patients’.<sup>100</sup> In 2004, it became apparent that Ministry of Health proposals to develop a strategy for the management of infected health care workers, published in 2001, were likely to be dropped from the health policy agenda.<sup>101</sup> As a consequence, the Medical Council found itself leading the policy response once again. It was not entirely convinced that this was appropriate; meeting minutes from October 2004 stated that ‘it could be argued that the Ministry of Health is better placed to provide the sort of macro policies that best protect the health and safety of the public’.<sup>102</sup>

In 2005, the Medical Council approached the Health Regulatory Authorities of New Zealand (HRANZ) to develop national guidelines on transmissible major viral infections for all registered health care workers.<sup>103</sup> The HRANZ guidelines were published in late 2005. Their stated purpose was to ‘best ensure a balance between safeguarding the public and safeguarding the rights of health care workers and infected health care workers’.<sup>104</sup> As in previous Medical Council policy statements, there was a strong emphasis on

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<sup>99</sup> *ibid.*

<sup>100</sup> *ibid.*

<sup>101</sup> Ministry of Health, *An Integrated Approach to Infectious Diseases: Priorities for Action 2002-2006*.

<sup>102</sup> MCNZ, ‘Major Transmissible Viral Infections’, 2004.

<sup>103</sup> HRANZ, ‘Transmissible major viral infections’, unpublished paper, 2005, in private possession.

HRANZ is an informal group made up of 15 registering health authorities, including the Medical Council of New Zealand, the Midwifery Council, and the Dental Council. It was established to oversee and manage matters of common interest under the 2003 Health Practitioners Competence Assurance Act, which protects the health and safety of the public by ensuring that health practitioners are fit and competent to practise.. Ministry of Health, ‘Confidence in your Health Practitioner’, available online, nd, at:

[http://www.moh.govt.nz/moh.nsf/wpg\\_index/Publications-confidence+in+your+health+practitioner](http://www.moh.govt.nz/moh.nsf/wpg_index/Publications-confidence+in+your+health+practitioner) (20 March 2009).

<sup>104</sup> HRANZ, ‘Transmissible major viral infections’, p.1.

adherence to standard precautions and infection control practices as the ‘most effective means of preventing transmission’ of blood borne viruses in the health care setting.<sup>105</sup> However, the 2005 HRANZ guidelines took a firmer approach towards hepatitis B immunisation and testing of those health care workers who performed exposure prone procedures.<sup>106</sup>

The guidelines stated that all health care workers who performed exposure prone procedures ‘*must*’ know their hepatitis B status, and that those with less than protective antibody levels should be referred for specialist advice.<sup>107</sup> Those who were infected should determine their hepatitis B e antigen and DNA status, and if positive, should not perform exposure prone procedures. Full duties could only resume after deliberation by a panel of medical experts with access to all relevant information. Mandatory hepatitis B screening, an integral component of UK policy for health care workers performing exposure prone procedures, was recommended ‘given the higher risk of transmission of [hepatitis B virus] and the availability of immunisation’. Mandatory disclosure of infectious status to patients, the subject of such contention in the US, was not required.<sup>108</sup>

The 2005 HRANZ guidelines provided clear guidance to health care workers and their employers that recognised the higher transmissibility of hepatitis B virus in the health care setting, and the need to protect the rights of both patients and health care workers. To what extent these recommendations have been implemented by DHBs is beyond the scope of this thesis. However, the HRANZ guidelines, which represented a broad professional consensus on the management of infected health care workers, provided the basis for consistent policies and protocols in DHBs nationwide. Furthermore, as the

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<sup>105</sup> *ibid.* ‘Standard precautions’, which were introduced by the CDC in 1996, amalgamated ‘universal precautions’ and isolation requirements for infectious conditions in a single set of guidelines. This development was credited with further reducing the risk of blood transmissions in the health care setting. J. S. Garner, ‘The Hospital Infection Control Practices Advisory Committee (HICPAC) guidelines for isolation precautions in hospitals, *Infection Control and Hospital Epidemiology*, 17, 1, 1996, pp.53-80.

<sup>106</sup> HRANZ, *HRANZ Joint Guidelines for Registered Health Care Workers on Transmissible Major Viral Infections*, 2005, p.2.

<sup>107</sup> A hepatitis B antibody titre over 10IU/L is considered protective against infection. Ministry of Health, *Immunisation Handbook 2006*, p.137.

<sup>108</sup> HRANZ, *HRANZ Joint Guidelines for Registered Health Care Workers on Transmissible Major Viral Infections*, p.2.

guidelines noted, the 2003 Health Practitioners Competence Assurance Act charged health practitioners' registration authorities with 'the primary responsibility of ... protect[ing] the health and safety of the public', and empowered them to 'ensure that the registered health practitioners for whom they are responsible are competent and fit to practise'.<sup>109</sup>

Post-2000, despite criticism from some quarters, the UK retained its stringent position on infected health care workers, updating its guidelines by integrating new scientific findings into existing policies. The CDC guidelines remained in limbo, calling into question a revised national policy acceptable to opposing sides of the debate. In 2005, by adopting a multidisciplinary approach to national policy development, New Zealand finally established a definitive position that emphasised the need for mandatory hepatitis B immunisation and closer regulation of hepatitis B infected health care workers.

### **Conclusion**

Prior to 1990, New Zealand's policies for the prevention of hepatitis B and HIV transmission were consistent with those of the US and the UK. When these policies diverged dramatically in the early 1990s, the New Zealand Health Department declined to take an authoritative stance on the issue of infected health care workers. The Medical Council of New Zealand, whose policies on viral transmission were strongly influenced by the 1991 CDC guidelines, provided guidance for doctors and their employers. However, even though the council adopted the voluntary approach to hepatitis B testing and immunisation taken by the CDC, it did not go so far as to recommend mandatory disclosure of a doctor's hepatitis B status.

The hepatitis B vaccine presented an effective means of preventing the spread of the virus, and in 1993 the UK health authorities introduced mandatory hepatitis B immunisation and testing of all staff performing exposure prone procedures. In the US and New Zealand, in the absence of mandatory immunisation policies, vaccine uptake among health care workers remained variable. Despite the benefits conferred by the

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<sup>109</sup> *ibid.*, p.1.

vaccine, the need to establish immune status after immunisation had the potential to reveal those workers who were infectious hepatitis B carriers. Consequently, during the 1990s, the New Zealand Medical Council and the CDC maintained a voluntary approach to hepatitis B immunisation, citing professional autonomy and freedom from stigma and discrimination as the basis for policy decisions.

Post-2000, the planned revision of the CDC guidelines has been abandoned, a reflection of the complex political, professional, ethical and legal issues that have impinged on this controversial area of policy making. In the UK, policies evolved in response to more accurate measures of viral infectivity and the introduction of new anti-viral therapies; nonetheless, the health authorities attempted to retain a balance between the public health interest and the rights and responsibilities of health care workers.

In New Zealand, the Ministry of Health withdrew from plans to formulate either a trans-Tasman policy or a national strategy on infected health care workers, prompting the Medical Council to approach HRANZ to develop policy applicable to all registered health care workers. Multidisciplinary decision making resulted in a marked shift in emphasis; in 2005, HRANZ formulated national guidelines that more closely emulated the UK model, with patient protection as a central policy concern. The extent to which these guidelines have been implemented remains unclear.





## CHAPTER TEN

### CONCLUSION

Between 1970 and 2005, New Zealand introduced an impressive number of policies to prevent hepatitis B. These policies covered areas as diverse as blood donor screening, occupational health and safety, immunisation, the screening for (detection) and screening of (surveillance) hepatitis B carriers, and the management of hepatitis B infected health care workers. Yet despite the Health Department's repeated refrain that New Zealand led the world in hepatitis B prevention, these policies did not represent a coordinated control strategy. On the contrary, this study shows that they evolved in an ad hoc fashion, as the Health Department (from 1993 the Ministry of Health) and successive governments responded to growing public, professional, and political pressure to act on hepatitis B.

Initially, New Zealand policy makers followed the approaches taken towards hepatitis B in other Western countries, where the prevalence of the disease was low. By the mid-1980s, however, the unexpected severity of the hepatitis B problem in New Zealand became apparent. Yet even though an effective vaccine was available and children were shown to be at high risk of contracting the disease, health officials did not advocate universal childhood immunisation. Factors other than scientific data and technical expertise shaped government responses: in the late 1980s the immunisation policy expanded according to political, economic, and social dynamics, rather than as part of a coherent plan for hepatitis B prevention. Equally, in the late 1990s, the government approved funding for the introduction of a national hepatitis B screening programme before the costs and benefits of the policy had been fully explored.

The thesis has developed a number of major themes explored in the earlier historiography of hepatitis B, and in historical works that have examined aspects of immunisation, screening and contemporary health policy. These include: the tenuous relationship between science and health policy, the reluctance of New Zealand health officials to act on hepatitis B, the rights of infected health workers versus the protection of the public

health, the role of individual policy players, and the influence of social, political and economic factors on the policy making process. Conclusions drawn from these themes will be discussed in turn, looking firstly at the tentative links between scientific research and hepatitis B policy.

While scientific research contributed to new understandings of the nature and spread of hepatitis B in New Zealand, it did not translate directly into policy changes. In the late 1960s, when the first hepatitis B test became available, new policy options became possible. However, research findings were filtered through pre-existing perceptions of the disease. In 1971, when the Health Department first declared hepatitis B a notifiable disease, transfusion recipients, health care workers and intravenous drug users were regarded as the groups at the highest risk of infection.<sup>1</sup> By 1973, blood bank statistics suggested an unexpected pattern of hepatitis B prevalence, with much higher rates of chronic carriage among Maori and Pacific people than among Europeans. Nevertheless, these findings were interpreted in the light of established medical beliefs around 'genetic susceptibility' to infectious disease, and the apparently fixed scientific 'facts' about the epidemiology of hepatitis B in Western countries.<sup>2</sup>

In the early 1980s, New Zealand's perceived first world health status, rather than the results of local prevalence studies, was the basis for government responses to proposals for the introduction of a hepatitis B immunisation programme. The development of an effective hepatitis B vaccine provided the means of preventing the disease; nevertheless, the Health Department maintained that it would have limited application in New Zealand, a developed country with a low prevalence of the disease. The Department was wary of formulating an immunisation policy in spite of research revealing that hepatitis B was endemic in some areas of the North Island, and that Maori children were at least three times as likely as European children to become infected and develop chronic hepatitis B

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<sup>1</sup> Anon., 'News: Serum Hepatitis'.

<sup>2</sup> See, for example, P. B. Booth, J. M. Staveley, 'Hepatitis-associated antigen testing by the New Zealand Blood Transfusion Services', p.63.

carriage.<sup>3</sup> The Department's guarded approach emphasised both the gap between epidemiological research and immunisation policy, and its dependence on international health authorities in immunisation matters. Rather than respond to the recommendations of the Epidemiology Advisory Committee (EAC) for an urgent start on a targeted childhood immunisation programme, senior health officials turned to the World Health Organization (WHO) for guidance.<sup>4</sup>

The disparities between science and policy became even more apparent later in the 1980s, when growing public pressure for state-funded childhood hepatitis B immunisation led the government to reconsider its policy options. In the lead up to a general election in 1987, attention turned to low dose hepatitis B vaccine as an economical alternative to the costly full dose vaccine. The cost savings involved provided the opportunity to expand the immunisation programme, nonetheless, the Communicable Disease Control Advisory Committee (CDCAC) opposed the use of vaccine in doses lower than the manufacturer recommended on the grounds that there was insufficient evidence of its efficacy.<sup>5</sup> In the event, political and economic priorities prevailed, and the government chose to expand state-funded immunisation to infants and preschoolers through the use of low dose vaccine.

Another theme has been the Health Department's reluctance to take a pro-active stance on hepatitis B control. Its dilatory approach to preventing the disease was evident from the early 1970s. Notwithstanding the importance of protecting transfusion recipients and maintaining the integrity of the trans-Tasman plasma exchange, the Transfusion Advisory Committee (TAC) faced unexplained bureaucratic delays during the introduction of the donor screening policy. Moreover, once screening was in place, tensions developed between the Department's focus on cost containment and the TAC's recommendations for more sensitive, albeit more expensive, screening tests.

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<sup>3</sup> A. Milne, 'Viral hepatitis in the eastern Bay of Plenty'; A. Milne, C. D. Moyes, 'Hepatitis B carriage in children'; Y. E. Hermon, I. K. Mushawar, M. I. Tobias, 'Hepatitis B infection in New Zealand children'.

<sup>4</sup> EAC minutes, 5 April 1984, AAFB 786, W3045/8.

<sup>5</sup> CDCAC minutes, 18 September 1986, Ministry of Health Archives, Wellington.

The Department's unwillingness to promote the introduction of hepatitis B immunisation in the early 1980s can be explained by its failure to adopt a new epidemiological framework for hepatitis B. Its failure to develop an integrated programme of hepatitis B control in the mid-1980s is more problematic. The fact that no senior figure within the Department acted as an advocate for hepatitis B prevention provides a partial explanation for the apparent disinterest in the findings of local prevalence studies. Nonetheless, there was no lack of advocacy by others; both the EAC and Alexander Milne, the leading lobbyist for childhood hepatitis B immunisation, called for an urgent response to the unexpectedly high prevalence of hepatitis B among New Zealand children.

The American historian of hepatitis B, William Muraskin, claimed that during the 1980s Milne's forceful personality and behaviour 'alienated many people in and around government'.<sup>6</sup> While Milne's assertive campaign for universal childhood hepatitis B immunisation undoubtedly challenged politicians and health officials, he did not determine the Department's reactive stance. Rather, caution and conservatism were characteristic of the health bureaucracy, which was perennially short of finance and manpower for public health programmes.<sup>7</sup> Hepatitis B had no visible impact in most New Zealand communities, and departmental officials rejected the notion that the disease presented a serious public health problem. Moreover, by the mid-1980s, hepatitis B was not the only issue competing for departmental attention; Acquired Immune Deficiency Syndrome (AIDS) was emerging as an international health concern.

There are clear similarities between AIDS and hepatitis B, yet AIDS engendered a sense of urgency and panic that motivated the Health Department to act.<sup>8</sup> Not only was it a new and deadly disease, but countries with which New Zealand was closely aligned, such as Australia, responded rapidly to prevent its spread. During the late 1980s, AIDS

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<sup>6</sup> W. Muraskin, 'Bucking the health establishment: Alexander Milne and the fight for a New Zealand hepatitis B immunization program', pp.215-6.

<sup>7</sup> See, for example, D. A. Dow, *Safeguarding the Public Health: A History of the New Zealand Department of Health*, p.207.

<sup>8</sup> Department of Health, Circular Letter No. Hosp 1983/82, 19 July 1983, 'Acquired immune deficiency syndrome and blood products'; Department of Health, Circular Letter No. Hosp 1983/109, 12 September 1983, 'Acquired Immunodeficiency Syndrome (AIDS)', ZABV A1073 92a.

overshadowed most other public health issues, including hepatitis B.<sup>9</sup> The knowledge that more than 60,000 New Zealanders had chronic hepatitis B virus infection while fewer than 120 AIDS cases had been notified had no discernible effect on policy makers.<sup>10</sup> In 1990, hepatitis B was bracketed with other vaccine-preventable diseases on the national immunisation schedule, and as such, gradually lost ground as a separate public health project.

The Health Department was also averse to developing policies for hepatitis B infected health care workers. In the early 1990s, in the wake of highly-publicised cases of hepatitis B and human immunodeficiency virus (HIV) transmission from infected health care workers to patients in the US and the UK, New Zealand health professionals looked to the Health Department for guidance. Unlike the US and UK health authorities, which were under intense public and political pressure to develop professional practice guidelines, the Department made no attempt to redefine its official position with regard to the rights of infected health care workers to continued employment, and the rights of the public to protection. Rather than confront the controversial issues of practice restriction, and hepatitis B testing and immunisation of health care workers, it absented itself from the policy making process. Policy was developed by default, by professional groups and organisations.<sup>11</sup> Moreover, post-2001, despite the Ministry of Health's stated goal of developing protocols for hepatitis B positive health care workers in collaboration with the Australian health authorities, these plans did not eventuate.<sup>12</sup>

The lack of government action on the potential risks posed by hepatitis B infected health care workers illustrated the political nature of the policy making process. In the early 1990s, with no reported cases of hepatitis B transmission from infected health care

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<sup>9</sup> AJHR, 1988, E.10. p.20.

<sup>10</sup> See, for example, E.W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*, p.57; AJHR, 1989, E.10, p.15.

<sup>11</sup> M. G. Thomas, 'Guidelines for health care workers who have hepatitis B virus or human immunodeficiency virus infection'; MCNZ, 'The Medical Council and transmission of major viral infections'.

<sup>12</sup> Ministry of Health, *An Integrated Approach to Infectious Disease: Priorities for Action 2002-2006*, p.27.

workers to patients in New Zealand, there was little urgency for the Health Department to address the issue of hepatitis B carriers in the health workforce. In the late 1990s, further reports of hepatitis B transmission from infected health care workers to patients were published in the US and the UK, highlighting the potential risks for patients undergoing surgical procedures. In New Zealand, where no such cases came to light, awareness of the problem was largely limited to the health professions. With no media focus on which to 'hang' the complex issues involved, debates over the management of infected health care workers took place outside the public arena. Consequently, the Ministry of Health, under no public or political pressure to act, put plans to deal with this potentially contentious area on hold.

Individuals, rather than the health authorities, instigated the introduction of policies to prevent and control hepatitis B. The importance of individual players in the policy process was evident from the early 1970s. Senior doctors, appointed to advisory committees on account of their medical expertise, provided the initial impetus for policy making. Their interest and influence reflected both the dominant role of the medical profession in health policy making and the perception that in New Zealand as in other Western countries, hepatitis B was confined largely to hospital settings. In 1971, leading transfusionist Dr John Staveley and other members of the TAC acted as the catalyst for the Health Department to introduce routine screening in New Zealand blood banks. Similarly, during the 1970s, the EAC, which comprised mainly senior hospital specialists, was instrumental in keeping the occupational hazards of hepatitis B for health care workers at the forefront of the policy agenda.

From the early 1980s onwards, Alexander Milne became increasingly influential as an advocate for the introduction of childhood hepatitis B immunisation. While Milne lacked medical qualifications, he gathered a core group of medical supporters, and he was highly effective as a single-issue health activist. By the mid-1980s, his media-savvy campaign for government-funded childhood hepatitis B immunisation had strong public and professional backing, while his audacious use of low dose vaccine attracted the attention of the international research community. Milne took a tactical approach to influencing

policy makers; in recognition of the weight given to the opinion of international medical experts, he regularly invited renowned hepatitis researchers to New Zealand to promote his cause. This strategy proved critical to the introduction of the 'low dose' infant and preschool immunisation policy.

Despite his success as a political lobbyist, however, Milne's expansive vision for hepatitis B control far exceeded the available funding and neglected the past experience and the capabilities of the public health workforce. In late 1987, he gained greater influence as a leading member of the official working party for the implementation of the hepatitis B preschool immunisation programme. Once in this role, Milne lobbied hard for an immediate start to immunisation. This was despite concerns expressed by CDCAC members, whose recent experience with the meningococcal A immunisation campaign made them wary of introducing a nationwide immunisation programme without sufficient lead-in time. In the event, the hasty start to the preschool campaign left little time for public health workers to consult with Maori communities or to develop immunisation initiatives to reach high risk preschoolers. Both of these factors contributed to the inadequate levels of immunisation coverage achieved among Maori children.<sup>13</sup>

In the policy vacuum that followed the preschool programme, Milne's campaign to expand hepatitis B immunisation to older children gained more ground than it might otherwise have done. Neither the government nor the Health Department took a strong lead in emphasising the importance of immunising babies and preschoolers to prevent infection and the development of hepatitis B carriage, or in providing sufficient resources to consolidate the existing immunisation programmes. In the absence of a clearly articulated central policy direction, individual health boards, private health providers and schools, disappointed by the results of the preschool campaign, began offering free or subsidised vaccine to school-aged children. At the same time, Milne continued his relentless round of lobbying. Milne seemed unstoppable; by the time the universal childhood immunisation policy was announced in late 1989, his focus had shifted to the

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<sup>13</sup> Health Research Services, *Hepatitis B Preschoolers Immunisation Campaign (1988/89) Process Evaluation*, ABQU 632 W4452/705 131/171/4 69791.

detection of hepatitis B carriers among high-risk school children. As a result of the confusion caused by this flurry of uncoordinated activity, fundamental aspects of the hepatitis B immunisation programme were neglected. In 1992, when the first immunisation coverage survey took place, fewer than half of Maori and Pacific two year olds had received a full course of hepatitis B vaccine.<sup>14</sup>

Leading Maori played an important part in raising the political profile of hepatitis B in the 1980s, but they had little input into the planning or delivery of immunisation policy. In late 1985, Dr Eru Pomare's ministerial report on hepatitis B pushed the disease up the policy agenda.<sup>15</sup> Nevertheless, health officials were highly selective in adopting his recommendations. Pomare's call for greater Maori participation 'at all levels of the decision making and implementation phases' of the policy process went unheeded, as did his request for 'community and cultural views' to be accommodated in decisions on hepatitis B policy.<sup>16</sup> Instead, strategies which had already had currency within the Department were implemented. In early 1987, the Government expanded state-funded hepatitis B immunisation to all infants in 'high risk health districts', as Pomare had advised, on the basis that targeting Maori as a high risk ethnic group would invite stigmatisation, and accusations of preferential treatment.<sup>17</sup> However, this approach was consistent with existing child health initiatives, such as the departmental programme delivered by Plunket nurses to preschoolers of all ethnicities in South Auckland, for which a primary objective was the improvement of health standards among Maori and Pacific children.<sup>18</sup>

In the 1990s, on the other hand, Maori politicians played a key role in the introduction of the hepatitis B screening policy. As a result of intense lobbying by Milne, Maori MPs of all political persuasions became strong proponents of a national screening programme.

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<sup>14</sup> NZCDC, 'Immunisation coverage in New Zealand: results of the regional immunization coverage surveys'.

<sup>15</sup> E. W. Pomare, *Hepatitis B: Report to the Minister of Health on the Eastern Bay of Plenty Immunisation Programme*.

<sup>16</sup> *ibid.*, pp.89-90.

<sup>17</sup> *ibid.*, p.89.

<sup>18</sup> See for example, L. Bryder, *A Voice for Mothers: The Plunket Society and Infant Welfare 1907-2000*, pp.236-40.



Milne's confrontational stance towards the medical establishment struck a chord with Maori, who regarded the disparities between Maori and non-Maori rates for chronic diseases, such as asthma and diabetes, as an indication of the failure of mainstream health services to meet Maori health needs.<sup>19</sup> In the mid-1990s, the Maori Affairs Committee was the political linchpin for the appointment of a second Ministry of Health working party on hepatitis B screening, while high ranking Maori politicians in the National New Zealand First Coalition Government (1996–1998) secured the funding required to launch the screening programme.

Economic factors were a consistent pressure on immunisation and screening policy. In the 1970s, the Health Department imposed stringent budgetary restrictions on screening, so that blood bank scientists were compelled to ration expensive commercial test reagents to stay abreast of internationally accepted transfusion practice. In the mid-1980s, the Health Department cited the high cost of the hepatitis B vaccine as the main deterrent to the expansion of the immunisation programme. The ongoing fiscal crises during the Fourth Labour Government (1984–1990) led to tighter controls on health expenditure, so that the cost reductions possible with low dose vaccine held a powerful appeal for policy makers. Equally, in the late 1980s, the decision to target preschoolers, rather than mount a more extensive school-based hepatitis B immunisation campaign as the CDCAC had recommended, was based primarily on financial factors.

This study spans a period of substantial health sector restructuring and reform, driven initially by the Labour Government, then, more vigorously, by the succeeding National Government (1990–1996). The change in political style initiated by Labour also had a marked effect on hepatitis B policy. Moves to reduce and target spending on social services in the late 1980s, which saw the consideration of part charges for health services, led the Health Department to approve a privately-run 'user pays' hepatitis B immunisation scheme for school children. This decision, which ran counter to the

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<sup>19</sup> M. Durie, *Whaiora: Maori Health Development*, p.205; E. W. Pomare, V. Keefe-Ormsby, C. Ormsby, N. Pearce, P. Reid, B. Robson and N. Watene-Haydon, *Hauora: Maori Standards of Health III, A study of the years 1970-91*, pp.159-65.

Department's 'mission' to reduce disparities in Maori health, and which was not applied to other childhood vaccines, led to a proliferation of private hepatitis B ventures, most of which failed to reach children from poorer backgrounds.<sup>20</sup> Maintaining equity of access to core public health services was cited as a major impetus for the subsequent expansion of the state-funded hepatitis B immunisation programme to school-aged children in 1990.

In the early 1990s, the health reforms, which were intended to increase financial efficiencies in the health sector, led to a greater emphasis on the prioritisation of public health interventions.<sup>21</sup> In its briefing on hepatitis B screening to the Maori Affairs Committee in 1995, among the objections raised by the Ministry of Health to the screening proposal was that during lengthy consultation over several years, neither Maori, nor the Ministry of Health, had identified hepatitis B as a Maori health priority.<sup>22</sup> While this argument did not sway the Maori Affairs Committee, it demonstrated the political shift away from 'behind the scenes' policy development, to a more explicit model of decision making.<sup>23</sup> Even so, those policy areas openly identified as public health priorities were not guaranteed political support; childhood immunisation, one of the key health strategies selected by the Public Health Commission in the mid-1990s, failed to attract strong political advocacy or adequate funding.<sup>24</sup> Consequently, during the late 1990s, overall immunisation coverage among New Zealand children fell short of projected targets, while the low immunisation rates among Maori and Pacific children showed few signs of improvement.<sup>25</sup>

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<sup>20</sup> M. Durie, *Whaiora: Maori Health Development*, p.105.

<sup>21</sup> See, for example, National Advisory Committee on Health and Disability, *Prioritising Health Services: A background paper for the National Health Committee*, Wellington, 2004, for an in-depth discussion of 'prioritisation' in the New Zealand health services, online, available at:

[http://www.moh.govt.nz/moh.nsf/pagescm/675/\\$File/prioritisation-backgroundpapers.pdf](http://www.moh.govt.nz/moh.nsf/pagescm/675/$File/prioritisation-backgroundpapers.pdf) (1 March 2010).

<sup>22</sup> Ministry of Health, *Briefing to the Maori Affairs Committee Hepatitis B Screening Programme for Maori*, pp.9-14.

<sup>23</sup> National Health Committee. *The best of health 3: are we doing the right things and are we doing the right things right?* Wellington, 1997, cited in National Advisory Committee on Health and Disability, *Prioritising Health Services: A background paper for the National Health Committee*.

<sup>24</sup> PHC, *Immunisation: The Public Health Commission's Advice to the Minister of Health 1993-1994*; PHC, *He Matariki: A Strategic Plan for Maori Health. He Kaupapa Whaingaroa Mo Te Hauora Tumatānui Maori. The Public Health Commission's Advice to the Minister of Health 1994-95*.

<sup>25</sup> W. Rainger, N. Solomon, N. Jones, J. Jarman, N. Turner, D. Lennon, J. Stewart, 'Immunisation coverage and risk factors for immunisation failure in Auckland and Northland'; Ministry of Health, *The National Immunization Coverage Survey 2005*.

Social changes that occurred from the 1970s onwards also impacted on the introduction and implementation of hepatitis B policy. The growing assertiveness of parents with regard to childhood immunisations, which was apparent in the strong public response to side-effects among children during the 1987 meningococcal A immunisation campaign, was one of the factors considered by the Health Department in selecting a suitable vaccine for the hepatitis B preschool programme.<sup>26</sup> Ultimately, however, a comparison of costs determined the choice of hepatitis B vaccine: blood-based vaccine in low doses was a cheaper option than full doses of the genetically-engineered product. The strong public reaction to the rumour that the blood-based vaccine was contaminated by AIDS illustrated both the heightened public sensitivity towards vaccine safety, and the Department's tardiness in taking account of the increasing knowledge of health consumers. The programme remained on track, but it took considerable time and effort to convince parents that the vaccine was free from contamination. Furthermore, evaluations of the preschool campaign included the 'AIDS scare' among the issues identified by parents and public health workers as deterrents to participation in the programme.<sup>27</sup>

The growth of the Maori self-determination movement in the late 1970s, which stimulated Maori to seek a more active role in health care, was also a factor in the formulation of hepatitis B policy.<sup>28</sup> In the early 1980s, the Health Department endorsed Maori aspirations to provide health services for Maori, citing Maori health as a public health priority and establishing a Maori health team.<sup>29</sup> While the Department acknowledged the principles of bicultural partnership, however, Maori had limited opportunities to engage in the design of health policy.<sup>30</sup> The Department's commitment

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<sup>26</sup> See, for example, F. Macdonald, 'Meningitis: Campaign goes astray'.

<sup>27</sup> L. Calder, *What is the best way to inform high-risk groups about hepatitis B immunisation? A survey by Polynesian health workers, South Auckland Health Development Unit*; Health Research Services, *Hepatitis B Preschoolers Immunisation Campaign (1988/89) Process Evaluation*, ABQU 632 W4452/705 131/171/4 69791.

<sup>28</sup> M. Durie, *Whaiora: Maori Health Development*, p.54; E. W. Pomare, V. Keefe-Ormsby, C. Ormsby, N. Pearce, P. Reid, B. Robson and N. Watene-Haydon, *Hauora: Maori Standards of Health III, A Study of the Years 1970-91*, pp.25-6.

<sup>29</sup> AJHR, 1984, E.10, p.23.

<sup>30</sup> Department of Health, Circular Memorandum, No 1986/70, cited in M. Durie, 'The Treaty of Waitangi and health care', p.283; see, also, R. Gauld, *Revolving Doors: New Zealand's Health Reforms – the Continuing Saga*, p.73; L. Bryder, 'Health Citizenship and "Closing the Gaps": Maori and Health Policy', p.56.

to biculturalism came into question in 1987 after the resignation of its Maori health team, which had liaised between Maori communities and policy makers.<sup>31</sup> The reasons for the team's resignation remain unclear, but its demise undoubtedly reduced Maori input into the policy process. Despite marked ethnic discrepancies in infection rates, the coordinator of the preschool campaign, a relatively new arrival to New Zealand, put little emphasis on engaging 'high risk' communities. For Maori, the low vaccine uptake among Maori preschoolers provided further proof of the inability of the public health services to address their specific health needs.<sup>32</sup>

By the mid-1990s, Maori had gained greater confidence in their ability to challenge the system and participate more fully in the health sector; however, the debates over hepatitis B screening showed that this was an uneven process.<sup>33</sup> In most other areas of primary health, Maori argued for a strong Maori voice and Maori control over the delivery of Maori health services. Yet the Maori Affairs Committee did not question Alexander Milne's claim that the Hepatitis Foundation, of which he was the director, was the most appropriate organisation to provide hepatitis B screening and follow up services for Maori carriers, on the grounds that the Foundation had wide experience in screening and in networking with Maori and Pacific communities.<sup>34</sup> Nor did Maori dispute his assertion that a pilot programme to test the cost-effectiveness and efficacy of a national screening programme was unnecessary. This was despite Maori involvement in pilot projects for the cervical cancer and breast screening programmes, both issues with particular relevance for Maori health.<sup>35</sup> Milne's controversial campaign to introduce population-based hepatitis B screening relied on high level advocacy by Maori, yet he did not

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<sup>31</sup> M. Durie, *Whaiora: Maori Health Development*, p.106.

<sup>32</sup> Ministerial Advisory Committee on Maori Health, *Hui Hauora Mokopuna: Ratana Pa, 22–24 June 1990*.

<sup>33</sup> M. Durie, *Mauri Ora: The Dynamics of Maori Health*, p.257.

<sup>34</sup> M. Aggett, 'Hepatitis B screening pros and cons debated', p.56.

<sup>35</sup> PHC, *He Matariki: A Strategic Plan for Maori Health. He Kaupapa Whaingā Roa Mo Te Hauora Tūmatanui Maori. The Public Health Commission's Advice to the Minister of Health 1994-95*, p.67; J. Chamberlain, *BreastScreen Aotearoa: An Independent Review*, 2002, online, nd, available at: [http://www.moh.govt.nz/moh.nsf/0/e5f49847be047806cc256c46007ee81d/\\$FILE/ChamberlainReview.pdf](http://www.moh.govt.nz/moh.nsf/0/e5f49847be047806cc256c46007ee81d/$FILE/ChamberlainReview.pdf) (27 March 2010); Ministry of Health, *A Brief Narrative on Maori Women and the National Cervical Screening Programme*, Wellington, 1997, online, nd, available at: [http://www.moh.govt.nz/notebook/nbbooks.nsf/8b635a98811e8aed85256ca8006d4e51/988b28df5c86944b4c2565d70018b69e/\\$FILE/whaitia.pdf](http://www.moh.govt.nz/notebook/nbbooks.nsf/8b635a98811e8aed85256ca8006d4e51/988b28df5c86944b4c2565d70018b69e/$FILE/whaitia.pdf) (27 March 2010).

promote a partnership model. When the three year programme ended in 2002, it fell far short of its initial targets, with only 28 per cent of eligible Maori screened.<sup>36</sup>

Future historical research could expand on the themes explored in this case study. The dominant role of economic, social and political factors in shaping the hepatitis B immunisation programme may have echoes in the introduction of the meningococcal B vaccination programme in the 1990s, another disease which impacted heavily on Maori and Pacific children. The influence of individuals on hepatitis B policy warrants comparison with other areas of health promotion, such as smoking cessation and AIDS prevention, where advocacy came from within the Ministry of Health as well as from community-based health activists. The history of hepatitis B screening raises the prospect of further research on the politics of Maori health, while the issues involved in the formulation of policy for hepatitis B infected workers could be amplified in a wider study of the consumer movement in health. Historical research in countries such as Taiwan, where hepatitis B vaccine was also introduced into the childhood schedule in the mid-1980s, would further illuminate the relationship between science and health policy.

This thesis, which examines the social, political and economic factors that have shaped hepatitis B policy in New Zealand, contributes to both the New Zealand and international historiography of hepatitis B, and adds to the growing body of historical literature on contemporary public health policy. While the New Zealand hepatitis B narrative is in many respects unique, there are clear links between the local experience and that of other Western countries, in particular the US and the UK. In contrast to previous studies of hepatitis B, this thesis places the development of local policy in an international context. By examining the history of hepatitis B policy within a broader social and political framework, it throws light on the complexities and contradictions of the policy making process, and shows how pre-existing interests, individual policy advocates, changing

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<sup>36</sup> T. Robinson, C. Bullen, W. Humphries, J. Hornell, C. D. Moyes, 'The New Zealand Hepatitis B Screening Programme: screening coverage and prevalence of chronic hepatitis B infection'. The programme targeted Maori, Pacific and Asian people from 15years of age in the North Island only.

interpretations of the disease, and competing priorities, rather than the apparently firm facts of scientific data and technical expertise, have contributed to policy decisions.

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